# SUBCHAPTER A—GENERAL PROVISIONS

## PART 1 [RESERVED]

## PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

### Subpart A—Introduction



### Subpart B—General Provisions



### Subpart C—Disclosures With Patient's Consent



### Subpart D—Disclosures Without Patient Consent



### Subpart E—Court Orders Authorizing Disclosure and Use



AUTHORITY: Sec. 408 of Pub. L. 92–255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub L. 93–282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94–237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94–581, 90 Stat. 2852; sec. 509 of Pub. L. 96–88, 93 Stat. 695; sec. 973(d) of Pub. L. 97–35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98–24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290ee–3) and sec. 333 of Pub. L. 91–616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93–282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94–581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98–24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290dd–3), as amended by sec. 131 of Pub. L. 102–321, 106 Stat. 368, (42 U.S.C. 290dd–2).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

## Subpart A—Introduction

### § 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98–24 to section 527 of the Public Health Service Act which is codified

at 42 U.S.C. 290ee–3. The amended statutory authority is set forth below:

§ 290ee–3. CONFIDENTIALITY OF PATIENT RECORDS.

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or witrhin those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not nore than $5,000 in the case of each subsequent offense.

(g) *Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94–581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

### § 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol

abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98–24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd–3. The amended statutory authority is set forth below:

§ 290dd–3. CONFIDENTIALITY OF PATIENT RECORDS

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of record of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) *Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94–581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

### § 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstances exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee–3(f), 42 U.S.C. 290dd–3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers* v. *United States,* 327 U.S. 614, 621–22, 66 S. Ct. 705, 707–08 (1946)).

### § 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee–3(f) and 42 U.S.C. 290dd–3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

### § 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

## Subpart B—General Provisions

### § 2.11 Definitions.

For purposes of these regulations:

*Alcohol abuse* means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

*Drug abuse* means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

*Diagnosis* means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

*Disclose or disclosure* means a communication of patient indentifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

*Informant* means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official: and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of

the program for the purpose of reporting the information obtained to the law enforcement agency or official.

*Patient* means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

*Patient identifying information* means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

*Person* means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

*Program* means:

(a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (See §2.12(e)(1) for examples.)

*Program director* means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

*Qualified service organization* means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the progams, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

*Records* means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

*Third party payer* means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

*Treatment* means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

*Undercover agent* means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

[52 FR 21809, June 9, 1987, as amended by 60 FR 22297, May 5, 1995]

### §2.12 Applicability.

(a) *General*—(1) *Restrictions on disclosure.* The restrictions on disclosure in

these regulations apply to any information, whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee–3(c), 42 U.S.C. 290dd–3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance.* An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*—(1) *Veterans' Administration.* These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and

those components of the Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

(i) Within a program or

(ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

(i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.* The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information*—(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see §2.17) or through patient access (see §2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

(i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;

(ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under §2.12(c)(3); and

(iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with §2.32 of these regulations.

(e) *Explanation of applicability*—(1) *Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms ''patient'' and ''program'' are defined in §2.11) if the program is federally assisted in any manner described in §2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as

providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment. However, these regulations would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or drug abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) *Federal assistance to program required.* If a patient's alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under §2.12(b), that patient's record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in §2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by these regulations unless the program itself received Federal assistance as defined by §2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under §2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987, as amended at 60 FR 22297, May 5, 1995]

### § 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgement of the presence of an identified patient in a facility or part of a facility if the

facility is not publicy identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgement does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

### §2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term ''minor'' means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

### §2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors*—(1) *Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the

guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients*—(1) *Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

### § 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

### § 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

### § 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

### § 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: ''Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]''; and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable

after the end of the retention period specified on the label, destroy the records.

### § 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee–3 and 42 U.S.C. 290dd–3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

### § 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These ''research privilege'' statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilage granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any imformation which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

### § 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon threreafter as the patient is capable of rational communication, each program shall:

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

(3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.

(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

(5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the

sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser *Unless:*

(1) The patient consents in writing:

(2) The disclosure is allowed by a court order; or

(3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd–3 and 42 U.S.C. 290ee–3 for Federal laws and 42 CFR part 2 for Federal regulations.)

(Approved by the Office of Management and Budget under control number 0930–0099)

### § 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

## Subpart C—Disclosures With Patient's Consent

### § 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) □ Request □ Authorize:
2. (name or general designation of program which is to make the disclosure)

3. To disclose: (kind and amount of information to be disclosed)

4. To: (name or title of the person or organization to which disclosure is to be made)

5. For (purpose of the disclosure)

6. Date (on which this consent is signed)

7. Signature of patient

8. Signature of parent or guardian (where required)

9. Signature of person authorized to sign in lieu of the patient (where required)

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

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### § 2.32 Prohibition on redisclosure.

*Notice to accompany disclosure.* Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2, 1987]

### § 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

### § 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Definitions.* For purposes of this section:

*Central registry* means an organization which obtains from two or more member progams patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

*Detoxification treatment* means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

*Maintenance treatment* means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

*Member program* means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information;

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of §2.31, except that:

(i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.

(d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and

(2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

### § 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of §2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified,

ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

## Subpart D—Disclosures Without Patient Consent

### § 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:

(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(2) The name of the individual making the disclosure;

(3) The date and time of the disclosure; and

(4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930–0099)

### § 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research;

(2) Has a research protocol under which the patient identifying information:

(i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and

(3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:

(i) The rights and welfare of patients will be adequately protected; and

(ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

### § 2.53 Audit and evaluation activities.

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

(1) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is

authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in §2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in §2.11, program includes an employee of, or provider of medical services under, the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a quality improvement organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(d) *Limitations on disclosure and use.* Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under §2.66 of these regulations.

## Subpart E—Court Orders Authorizing Disclosure and Use

### § 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee–3, 42 U.S.C. 290dd–3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

### § 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

### § 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:

(1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;

(2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or

(3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(b) [Reserved]

### § 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrunity.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a

manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

### § 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under §2.66 is sought with an order under this section, the person holding the records must be given:

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and

(3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be

represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

### §2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) *Application.* (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of §2.31 of these regulations) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of §2.64 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information:* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under §2.65 of these regulations.

### §2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under §2.65 of these regulations.

# PART 2a—PROTECTION OF IDENTITY—RESEARCH SUBJECTS

Sec.



AUTHORITY: Sec. 3(a), Pub. L. 91–513 as amended by sec. 122(b), Pub. L. 93–282; 84 Stat. 1241 (42 U.S.C. 242a(a)), as amended by 88 Stat. 132.

SOURCE: 44 FR 20384, Apr. 4, 1979, unless otherwise noted.

## §2a.1 Applicability.

(a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) provides that ''[t]he Secretary [of Health and Human Services] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.'' The regulations in this part establish procedures under which any person engaged in research on mental health including research on the use and effect of alcohol and other psychoactive drugs (whether or not the research is federally funded) may, subject to the exceptions set forth in paragraph (b) of this section, apply for such an authorization of confidentiality.

(b) These regulations do not apply to:

(1) Authorizations of confidentiality for research requiring an Investigational New Drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or to approved new drugs, such as methadone, requiring continuation of long-

term studies, records, and reports. Attention is called to 21 CFR 291.505(g) relating to authorizations of confidentiality for patient records maintained by methadone treatment programs.

(2) Authorizations of confidentiality for research which are related to law enforcement activities or otherwise within the purview of the Attorney General's authority to issue authorizations of confidentiality pursuant to section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)) and 21 CFR 1316.21.

(c) The Secretary's regulations on confidentiality of alcohol and drug abuse patient records (42 CFR part 2) and the regulations of this part may, in some instances, concurrently cover the same transaction. As explained in 42 CFR 2.24 and 2.24–1, 42 CFR part 2 restricts voluntary disclosures of information from applicable patient records while a Confidentiality Certificate issued pursuant to the regulations of this part protects a person engaged in applicable research from being compelled to disclose identifying characteristics of individuals who are the subject of such research.

### § 2a.2 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(b) *Person* means any individual, corporation, government, or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(c) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations.

(d) *Drug* has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(e) *Controlled drug* means a drug which is included in schedule I, II, III, IV, or V of part B of the Controlled Substances Act (21 U.S.C. 811–812).

(f) *Administer* refers to the direct application of a drug to the body of a human research subject, whether such application be by injection, inhalation, ingestion, or any other means, by (1) a qualified person engaged in research (or, in his or her presence, by his or her authorized agent), or (2) a research subject in accordance with instructions of a qualified person engaged in research, whether or not in the presence of a qualified person engaged in research.

(g) *Identifying characteristics* refers to the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.

(h) *Psychoactive drug* means, in addition to alcohol, any drug which has as its principal action an effect on thought, mood, or behavior.

### § 2a.3 Application; coordination.

(a) Any person engaged in (or who intends to engage in) the research to which this part applies, who desires authorization to withhold the names and other identifying characteristics of individuals who are the subject of such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director, National Institute on Drug Abuse, the Office of the Director, National Institute of Mental Health, or the Office of the Director, National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Maryland 20857 for an authorization of confidentiality.

(b) If there is uncertainty with regard to which Institute is appropriate or if the research project falls within the purview of more than one Institute, an application need be submitted only to one Institute. Persons who are uncertain with regard to the applicability of these regulations to a particular type of research may apply for an authorization of confidentiality under the regulations of this part to one of the Institutes. Requests which are within the scope of the authorities described

in §2a.1(b) will be forwarded to the appropriate agency for consideration and the person will be advised accordingly.

(c) An application may accompany, precede, or follow the sumission of a request for DHHS grant or contract assistance, though it is not necessary to request DHHS grant or contract assistance in order to apply for a Confidentiality Certificate. If a person has previously submitted any information required in this part in connection with a DHHS grant or contract, he or she may substitute a copy of information thus submitted, if the information is current and accurate. If a person requests a Confidentiality Certificate at the same time he or she submits an application for DHHS grant or contract assistance, the application for a Confidentiality Certificate may refer to the pertinent section(s) of the DHHS grant or contract application which provide(s) the information required to be submitted under this part. (See §§2a.4 and 2a.5.)

(d) A separate application is required for each research project for which an authorization of confidentiality is requested.

### §2a.4 Contents of application; in general.

In addition to any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project shall contain:

(a) The name and address of the individual primarily responsible for the conduct of the research and the sponsor or institution with which he or she is affiliated, if any. Any application from a person affiliated with an institution will be considered only if it contains or is accompanied by documentation of institutional approval. This documentation may consist of a written statement signed by a responsible official of the institution or of a copy of or reference to a valid certification submitted in accordance with 45 CFR part 46.

(b) The location of the research project and a description of the facilities available for conducting the research, including the name and address of any hospital, institution, or clinical laboratory facility to be utilized in connection with the research.

(c) The names, addresses, and summaries of the scientific or other appropriate training and experience of all personnel having major responsibilities in the research project and the training and experience requirements for major positions not yet filled.

(d) An outline of the research protocol for the project including a clear and concise statement of the purpose and rationale of the research project and the general research methods to be used.

(e) The date on which research will begin or has begun and the estimated date for completion of the project.

(f) A specific request, signed by the individual primarily responsible for the conduct of the research, for authority to withhold the names and other identifying characteristics of the research subjects and the reasons supporting such request.

(g) An assurance (1) From persons making application for a Confidentiality Certificate for a research project for which DHHS grant or contract support is received or sought that they will comply with all the requirements of 45 CFR part 46, ''Protection of Human Subjects,'' or

(2) From all other persons making application that they will comply with the informed consent requirements of 45 CFR 46.103(c) and document legally effective informed consent in a manner consistent with the principles stated in 45 CFR 46.110, if it is determined by the Secretary, on the basis of information submitted by the person making application, that subjects will be placed at risk. If a modification of paragraphs (a) or (b) of 45 CFR 46.110 is to be used, as permitted under paragraph (c) of that section, the applicant will describe the proposed modification and submit it for approval by the Secretary.

(h) An assurance that if an authorization of confidentiality is given it will not be represented as an endorsement of the research project by the Secretary or used to coerce individuals to participate in the research project.

(i) An assurance that any person who is authorized by the Secretary to protect the privacy of research subjects

will use that authority to refuse to disclose identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects.

(j) An assurance that all research subjects who participate in the project during the period the Confidentiality Certificate is in effect will be informed that:

(1) A Confidentiality Certificate has been issued;

(2) The persons authorized by the Confidentiality Certificate to protect the identity of research subjects may not be compelled to identify research subjects in any civil, criminal, administrative, legislative, or other proceedings whether Federal, State, or local;

(3) If any of the following conditions exist the Confidentiality Certificate does not authorize any person to which it applies to refuse to reveal identifying information concerning research subjects:

(i) The subject consents in writing to disclosure of identifying information,

(ii) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or regulations promulgated thereunder (title 21, Code of Federal Regulations), or

(iii) Authorized personnel of DHHS request identifying information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See §2a.7(b));

(4) The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects;

(5) The Confidentiality Certificate does not represent an endorsement of the research project by the Secretary.

(k) An assurance that all research subjects who enter the project after the termination of the Confidentiality Certificate will be informed that the authorization of confidentiality has ended and that the persons authorized to protect the identity of research subjects by the Confidentiality Certificate may not rely on the Certificate to refuse to disclose identifying characteristics of research subjects who were not participants in the project during the period the Certificate was in effect. (See §2a.8(c)).

### §2a.5 Contents of application; research projects in which drugs will be administered.

(a) In addition to the information required by §2a.4 and any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project which involves the administering of a drug shall contain:

(1) Identification of the drugs to be administered in the research project and a description of the methods for such administration, which shall include a statement of the dosages to be administered to the research subjects;

(2) Evidence that individuals who administer drugs are authorized to do so under applicable Federal and State law; and

(3) In the case of a controlled drug, a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

(b) An application for an authorization of confidentiality with respect to a research project which involves the administering of a controlled drug may include a request for exemption of persons engaged in the research from State or Federal prosecution for possession, distribution, and dispensing of controlled drugs as authorized under section 502(d) of the Controlled Substances Act (21 U.S.C. 872(d)) and 21 CFR 1316.22. If the request is in such form, and is supported by such information, as is required by 21 CFR 1316.22, the Secretary will forward it, together with his or her recommendation that such request be approved or disapproved, for the consideration of the Administrator of the Drug Enforcement Administration.

### §2a.6 Issuance of Confidentiality Certificates; single project limitation.

(a) In reviewing the information provided in the application for a Confidentiality Certificate, the Secretary will take into account:

(1) The scientific or other appropriate training and experience of all personnel having major responsibilities in the research project;

(2) Whether the project constitutes bona fide ''research'' which is within the scope of the regulations of this part; and

(3) Such other factors as he or she may consider necessary and appropriate. All applications for Confidentiality Certificates shall be evaluated by the Secretary through such officers and employees of the Department and such experts or consultants engaged for this purpose as he or she determines to be appropriate.

(b) After consideration and evaluation of an application for an authorization of confidentiality, the Secretary will either issue a Confidentiality Certificate or a letter denying a Confidentiality Certificate, which will set forth the reasons for such denial, or will request additional information from the person making application. The Confidentiality Certificate will include:

(1) The name and address of the person making application;

(2) The name and address of the individual primarily responsible for conducting the research, if such individual is not the person making application;

(3) The location of the research project;

(4) A brief description of the research project;

(5) A statement that the Certificate does not represent an endorsement of the research project by the Secretary;

(6) The Drug Enforcement Administration registration number for the project, if any; and

(7) The date or event upon which the Confidentiality Certificate becomes effective, which shall not be before the later of either the commencement of the research project or the date of issuance of the Certificate, and the date or event upon which the Certificate will expire.

(c) A Confidentiality Certificate is not transferable and is effective only with respect to the names and other identifying characteristics of those individuals who are the subjects of the single research project specified in the Confidentiality Certificate. The recipient of a Confidentiality Certificate shall, within 15 days of any completion or discontinuance of the research project which occurs prior to the expiration date set forth in the Certificate, provide written notification to the Director of the Institute to which application was made. If the recipient determines that the research project will not be completed by the expiration date set forth in the Confidentiality Certificate he or she may submit a written request for an extension of the expiration date which shall include a justification for such extension and a revised estimate of the date for completion of the project. Upon approval of such a request, the Secretary will issue an amended Confidentiality Certificate.

(d) The protection afforded by a Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate (e.g., changes in the personnel having major responsibilities in the research project, major changes in the scope or direction of the research protocol, or changes in the drugs to be administered and the persons who will administer them). The recipient of a Confidentiality Certificate shall notify the Director of the Institute to which application was made of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application. On the basis of such application and other pertinent information the Secretary will either:

(1) Approve the amended application and issue an amended Confidentiality Certificate together with a Notice of Cancellation terminating original the Confidentiality Certificate in accordance with § 2a.8; or

(2) Disapprove the amended application and notify the applicant in writing that adoption of the proposed significant changes will result in the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with § 2a.8.

### § 2a.7 Effect of Confidentiality Certificate.

(a) A Confidentiality Certificate authorizes the withholding of the names and other identifying characteristics of

individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances:

(1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information,

(2) Authorized personnel of DHHS request such information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 for confidentiality standards imposed on such DHHS personnel), or

(3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

### §2a.8 Termination.

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See §2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

## PART 3 [RESERVED]

## PART 4—NATIONAL LIBRARY OF MEDICINE

Sec.



AUTHORITY: 42 U.S.C. 216, 286.

SOURCE: 56 FR 29188, June 26, 1991, unless otherwise noted.

### §4.1 Programs to which these regulations apply.

(a) The regulations of this part govern access to the National Library of Medicine's facilities and library collections and the availability of its bibliographic, reproduction, reference, and

related services. These functions are performed by the Library directly for the benefit of the general public and health-sciences professionals as required by sections 465(b) (3)–(6) of the Act (42 U.S.C. 286(b) (3)–(6)).

(b) The regulations of this part do not apply to:

(1) The Library's internal functions relating to the acquisition and preservation of materials and the organization of these materials as required by sections 465(b) (1) and (2) of the Act (42 U.S.C. 286(b) (1) and (2)).

(2) The availability of ''records'' under the Freedom of Information Act or the Privacy Act of 1974 (5 U.S.C. 552, 552a). These matters are covered in 45 CFR parts 5 and 5b.

(3) Federal assistance for medical libraries and other purposes which are authorized by sections 469–477 of the Act (42 U.S.C. 286b to 286b–8). (See parts 59a, 61 and 64 of this chapter.)

(4) The availability of facilities, collections, and related services of Regional Medical Libraries established or maintained under the authority in section 475 of the Act (42 U.S.C. 286b–6). (See part 59a, subpart B of this chapter.)

### § 4.2 Definitions.

As used in this part:

*Act* means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

*Collections* means all books, periodicals, prints, audiovisual materials, films, videotapes, recordings, manuscripts, and other resource materials of the library. It does not include data processing tapes or programs used solely for internal processing activities to generate reference materials, nor does it include ''records'' of the Library as defined in 45 CFR 5.5. Records of the Library are available in accordance with the regulations under the Freedom of Information Act and Privacy Act of 1974. (See 45 CFR parts 5 and 5b.)

*Director* means the Director of the National Library of Medicine or the Director's delegate.

*Health-sciences professional* means any person engaged in: (1) The administration of health activities; (2) the provision of health services; or (3) research, teaching, or education concerned with the advancement of medicine or other sciences related to health or improvement of the public health.

*Historical collection* means: (1) Materials in the collections published or printed prior to 1914; (2) manuscripts and prints; (3) the archival film collection; and (4) other materials of the collections which, because of age, or unique or unusual value, require special handling, storage, or protection for their preservation, as determined by the Director.

*Library* means the National Library of Medicine, established by section 465 of the Act (42 U.S.C. 286).

*Regional Medical Library* means a medical library established or maintained as a regional medical library under section 475 of the Act (42 U.S.C. 286b–6).

### § 4.3 Purpose of the Library.

The purpose of the Library is to assist the advancement of medical and related sciences and aid the dissemination and exchange of scientific and other information important to the progress of medicine and the public health. The Library acquires and maintains library materials pertinent to medicine, including audiovisual materials; compiles, publishes, and disseminates catalogs, indices, and bibliographies of these materials, as appropriate; makes available materials, through loan or otherwise; provides reference and other assistance to research; and engages in other activities in furtherance of this purpose.

### § 4.4 Use of Library facilities.

(a) *General.* The Library facilities are available to any person seeking to make use of the collections. The Director may prescribe reasonable rules to assure the most effective use of facilities by health-sciences professionals and to protect the collections from misuse or damage. These rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination.

(b) *Reading rooms.* Public reading rooms are available for obtaining and reading materials from the collections. The Director may prescribe reasonable rules designed to provide adequate

reading space and orderly conditions and procedures.

(c) *Study rooms.* Upon request a limited number of study rooms may be made available to individuals requiring extensive use of Library materials. Requests for study rooms shall be addressed in writing to the Director. The Director shall give priority, in the following order, for study room use to:

(1) Persons engaged in ''special scientific projects'' under section 473 of the Act (42 U.S.C. 286b–4),

(2) Health-sciences professionals, and

(3) The general public.

### §4.5 Use of materials from the collections.

(a) *Unrestricted materials.* Except as otherwise provided in this section, materials from the collections are generally available to any interested person only in facilities provided by the Library for this purpose. The Director may prescribe additional reasonable rules to assure the most effective use of the Library's resources by health-sciences professionals and to protect the collections from misuse or damage. The rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination. Materials in the collections are available upon each request which assures, to the Director's satisfaction, that the materials will be safeguarded from misuse, damage, loss, or misappropriation, and will be returned promptly after use or upon request of the Library.

(b) *Restricted materials*—(1) *Historical collection.* Materials from the historical collection are available only as the Director may permit to assure their maximum preservation and protection. Copies of these materials may be made available in the form of microfilm and other copies, for which reasonable fees may be charged.

(2) *Gifts.* Materials in the collections are available only in accordance with any limitations imposed as a condition of the acquisition of those materials, whether the acquisition was by gift or purchase.

(c) *Loans*—(1) *General.* Requests for loans of materials must assure the Library that (i) the materials will be safeguarded from misuse, damage, loss, or misappropriation and (ii) the materials will be returned promptly after use or upon request of the Library. The Library may provide copies in lieu of original materials, which need not be returned unless otherwise stated at the time of the loan.

(2) *Loans of audiovisual materials.* Audiovisual materials are available for loan under the same general terms as printed materials.

(3) *Loans to other libraries.* Upon request materials or copies are available for use through libraries of public or private agencies or institutions. The requesting library must assure that it has first exhausted its own collection resources, those of other local libraries in the geographic area, and those of the Regional Medical Library network (including Regional and Resource Libraries) before making a request for a loan.

(4) *Loans to health-sciences professionals.* The Director may make loans of materials directly to health-sciences professionals. An individual wishing a loan of library materials must assure to the satisfaction of the Director that the individual is geographically isolated, in terms of distance or available transportation, from medical literature resources likely to contain the desired material.

(Approved by the Office of Management and Budget under control number 0925–0276)

### §4.6 Reference, bibliographic, reproduction, and consultation services.

(a) *General.* To the extent resources permit, the Library will make available, upon request, reference, bibliographic, reproduction, and consultation services. Priority will be given to requests from health-sciences professionals for services not reasonably available through local or regional libraries.

(b) *Specialized bibliographic services.* The Director may provide bibliographies on individually selected medical or scientific topics upon request where it is consistent with the Library's purpose. The Director may publish and make available for general distribution by the Library, bibliographic searches determined to be of general interest. The Library may also produce

and distribute a limited number of bibliographies on topics of general interest to public or nonprofit health-related professional societies, research organizations, and other group users. These bibliographies may be produced on a regularly recurring or intermittent basis under contract between the Library and public or nonprofit agencies, when determined in each case by the Director to be necessary to assure more effective distribution of the bibliographic information.

(c) *Information retrieval system computer tapes.* To the extent Library resources permit and in order to further the Library's purpose, the Director may make available upon request by agencies, organizations, and institutions copies of all or part of the Library's magnetic tapes.

### § 4.7 Fees.

The Director may charge reasonable fees for any service provided by the Library under this part, in accordance with a schedule available at the Library upon request, which are designed to recover all or a portion of the cost to the Library of providing the service.

### § 4.8 Publication of the Library and information about the Library.

Lists of bibliographies, Library publications sold by the Government Printing Office, necessary application forms, and other information concerning the organization, operation, functions, and services of the Library, are available from the National Library of Medicine, Bethesda, Maryland 20894.

## PART 5—DESIGNATION OF HEALTH PROFESSIONAL(S) SHORTAGE AREAS

Sec.



AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sec. 332 of the Public Health Service Act, 90 Stat. 2270–2272 (42 U.S.C. 254e).

SOURCE: 45 FR 76000, Nov. 17, 1980, unless otherwise noted.

### § 5.1 Purpose.

These regulations establish criteria and procedures for the designation of geographic areas, population groups, medical facilities, and other public facilities, in the States, as health professional(s) shortage areas.

### § 5.2 Definitions.

*Act* means the Public Health Service Act, as amended.

*Health professional(s) shortage area* means any of the following which the Secretary determines has a shortage of health professional(s): (1) An urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services); (2) a population group; or (3) a public or nonprofit private medical facility.

*Health service area* means a health service area whose boundaries have been designated by the Secretary, under section 1511 of the Act, for purposes of health planning activities.

*Health systems agency* or *HSA* means the health systems agency designated, under section 1515 of the Act, to carry out health planning activities for a specific health service area.

*Medical facility* means a facility for the delivery of health services and includes: (1) A community health center, public health center, outpatient medical facility, or community mental health center; (2) a hospital, State mental hospital, facility for long-term

care, or rehabilitation facility; (3) a migrant health center or an Indian Health service facility; (4) a facility for delivery of health services to inmates in a U.S. penal or correctional institution (under section 323 of the Act) or a State correctional institution; (5) a Public Health Service medical facility (used in connection with the delivery of health services under section 320, 321, 322, 324, 325, or 326 of the Act); or (6) any other Federal medical facility.

*Metropolitan area* means an area which has been designated by the Office of Management and Budget as a standard metropolitan statistical area (SMSA). All other areas are ''non-metropolitan areas.''

*Poverty level* means the povery level as defined by the Bureau of the Census, using the poverty index adopted by a Federal Interagency Committee in 1969, and updated each year to reflect changes in the Consumer Price Index.

*Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department to whom the authority involved has been delegated.

*State* includes, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

*State health planning and development agency* or *SHPDA* means a State health planning and development agency designated under section 1521 of the Act.

### §5.3 Procedures for designation of health professional(s) shortage areas.

(a) Using data available to the Department from national, State, and local sources and based upon the criteria in the appendices to this part, the Department will annually prepare listings (by State and health service area) of currently designated health professional(s) shortage areas and potentially designatable areas, together with appropriate related data available to the Department. Relevant portions of this material will then be forwarded to each health systems agency, State health planning and development agency, and Governor, who will be asked to review the listings for their State, correct any errors of which they are aware, and offer their recommendations, if any, within 90 days, as to which geographic areas, population groups, and facilities in areas under their jurisdiction should be designated. An information copy of these listings will also be made available, upon request, to interested parties for their use in providing comments or recommendations to the Secretary and/or to the appropriate HSA, SHPDA, or Governor.

(b) In addition, any agency or individual may request the Secretary to designate (or withdraw the designation of) a particular geographic area, population group, or facility as a health professional(s) shortage area. Each request will be forwarded by the Secretary to the appropriate HSA, SHPDA, and Governor, who will be asked to review it and offer their recommendations, if any, within 30 days. An information copy will also be made available to other interested parties, upon request, for their use in providing comments or recommendations to the Secretary and/or to the appropriate HSA, SHPDA, or Governor.

(c) In each case where the designation of a public facility (including a Federal medical facility) is under consideration, the Secretary will give written notice of the proposed designation to the chief administrative officer of the facility, who will be asked to review it and offer their recommendations, if any, within 30 days.

(d) After review of the available information and consideration of the comments and recommendations submitted, the Secretary will designate health professional(s) shortage areas and withdraw the designation of any areas which have been determined no longer to have a shortage of health professional(s).

### §5.4 Notification and publication of designations and withdrawals.

(a) The Secretary will give written notice of the designation (or withdrawal of designation) of a health professional(s) shortage area, not later than 60 days from the date of the designation (or withdrawal of designation), to:

(1) The Governor of each State in which the area, population group, medical facility, or other public facility so designated is in whole or in part located;

(2) Each HSA for a health service area which includes all or any part of the area, population group, medical facility, or other public facility so designated;

(3) The SHPDA for each State in which the area, population group, medical facility, or other public facility so designated is in whole or in part located; and

(4) Appropriate public or nonprofit private entities which are located in or which have a demonstrated interest in the area so designated.

(b) The Secretary will periodically publish updated lists of designated health professional(s) shortage areas in the FEDERAL REGISTER, by type of professional(s) shortage. An updated list of areas for each type of professional(s) shortage will be published at least once annually.

(c) The effective date of the designation of an area shall be the date of the notification letter to the individual or agency which requested the designation, or the date of publication in the FEDERAL REGISTER, whichever comes first.

(d) Once an area is listed in the FEDERAL REGISTER as a designated health professional(s) shortage area, the effective date of any later withdrawal of the area's designation shall be the date when notification of the withdrawal, or an updated list of designated areas which does not include it, is published in the FEDERAL REGISTER.

## APPENDIX A TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PRIMARY MEDICAL CARE PROFESSIONAL(S)

### *Part I—Geographic Areas*

A. *Federal and State Correctional Institutions.*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of primary medical care professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE primary care physicians serving the institution is at least 1,000:1.

Here the number of internees is defined as follows:

(i) If the number of new inmates per year and the average length-of-stay are not specified, or if the information provided does not indicate that intake medical examinations are routinely performed upon entry, then—Number of internees=average number of inmates.

(ii) If the average length-of-stay is specified as one year or more, and intake medical examinations are routinely performed upon entry, then—Number of internees=average number of inmates+(0.3)×number of new inmates per year.

(iii) If the average length-of-stay is specified as less than one year, and intake examinations are routinely performed upon entry, then—Number of internees=average number of inmates+(0.2)×(1+ALOS/2)×number of new inmates per year where ALOS=average length-of-stay (in fraction of year). (The number of FTE primary care physicians is computed as in part I, section B, paragraph 3 above.)

2. Determination of Degree of Shortage.

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to primary care physicians, as follows:

Group 1—Institutions with 500 or more inmates and no physicians.

Group 2—Other institutions with no physicians and institutions with R greater than (or equal to) 2,000:1.

Group 3—Institutions with R greater than (or equal to) 1,000:1 but less than 2,000:1.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Primary Medical Care Services.*

(a) The following areas will be considered rational areas for the delivery of primary medical care services:

(i) A county, or a group of contiguous counties whose population centers are within 30 minutes travel time of each other.

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns, distinctive population characteristics or other factors, has limited access to contiguous area resources, as measured generally by a travel time greater than 30 minutes to such resources.

(iii) Established neighborhoods and communities within metropolitan areas which display a strong self-identity (as indicated

by a homogeneous socioeconomic or demographic structure and/or a tradition of interaction or interdependency), have limited interaction with contiguous areas, and which, in general, have a minimum population of 20,000.

(b) The following distances will be used as guidelines in determining distances corresponding to 30 minutes travel time:

(i) Under normal conditions with primary roads available: 20 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 15 miles.

(iii) In flat terrain or in areas connected by interstate highways: 25 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 30 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions, with the following adjustments, where appropriate:

(a) Adjustments to the population for the differing health service requirements of various age-sex population groups will be computed using the table below of visit rates for 12 age-sex population cohorts. The total expected visit rate will first be obtained by multiplying each of the 12 visit rates in the table by the size of the area population within that particular age-sex cohort and adding the resultant 12 visit figures together. This total expected visit rate will then be divided by the U.S. average per capita visit rate of 5.1, to obtain the adjusted population for the area.

| Sex | Age groups | | | | | |
|---|---|---|---|---|---|---|
| | Under 5 | 5–14 | 15–24 | 25–44 | 45–64 | 65 and over |
| Male ..... | 7.3 | 3.6 | 3.3 | 3.6 | 4.7 | 6.4 |
| Female .. | 6.4 | 3.2 | 5.5 | 6.4 | 6.5 | 6.8 |

(b) The effect of transient populations on the need of an area for primary care professional(s) will be taken into account as follows:

(i) Seasonal residents, i.e., those who maintain a residence in the area but inhabit it for only 2 to 8 months per year, may be included but must be weighted in proportion to the fraction of the year they are present in the area.

(ii) Other tourists (non-resident) may be included in an area's population but only with a weight of 0.25, using the following formula: Effective tourist contribution to population=0.25×(fraction of year tourists are present in area)×(average daily number of tourists during portion of year that tourists are present).

(iii) Migratory workers and their families may be included in an area's population, using the following formula: Effective migrant contribution to population=(fraction of year migrants are present in area)×(average daily number of migrants during portion of year that migrants are present).

3. *Counting of Primary Care Practitioners.*

(a) All non-Federal doctors of medicine (M.D.) and doctors of osteopathy (D.O.) providing direct patient care who practice principally in one of the four primary care specialities—general or family practice, general internal medicine, pediatrics, and obstetrics and gynecology—will be counted. Those physicians engaged solely in administration, research, and teaching will be excluded. Adjustments for the following factors will be made in computing the number of full-time-equivalent (FTE) primary care physicians:

(i) Interns and residents will be counted as 0.1 full-time equivalent (FTE) physicians.

(ii) Graduates of foreign medical schools who are not citizens or lawful permanent residents of the United States will be excluded from physician counts.

(iii) Those graduates of foreign medical schools who are citizens or lawful permanent residents of the United States, but do not have unrestricted licenses to practice medicine, will be counted as 0.5 FTE physicians.

(b) Practitioners who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who provide patient care services to the residents of the area only on a part-time basis will be discounted through the use of full-time equivalency figures. A 40-hour work week will be used as the standard for determining full-time equivalents in these cases. For practitioners working less than a 40-hour week, every four (4) hours (or ½ day) spent providing patient care, in either ambulatory or inpatient settings, will be counted as 0.1 FTE (with numbers obtained for FTE's rounded to the nearest 0.1 FTE), and each physician providing patient care 40 or more hours a week will be counted as 1.0 FTE physician. (For cases where data are available only for the number of hours providing patient care in office settings, equivalencies will be provided in guidelines.)

(c) In some cases, physicians located within an area may not be accessible to the population of the area under consideration. Allowances for physicians with restricted practices can be made, on a case-by-case basis. However, where only a portion of the population of the area cannot access existing primary care resources in the area, a population group designation may be more appropriate (see part II of this appendix).

(d) Hospital staff physicians involved exclusively in inpatient care will be excluded.

The number of full-time equivalent physicians practicing in organized outpatient departments and primary care clinics will be included, but those in emergency rooms will be excluded.

(e) Physicians who are suspended under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act for a period of eighteen months or more will be excluded.

4. *Determination of Unusually High Needs for Primary Medical Care Services.*

An area will be considered as having unusually high needs for primary health care services if at least one of the following criteria is met:

(a) The area has more than 100 births per year per 1,000 women aged 15–44.

(b) The area has more than 20 infant deaths per 1,000 live births.

(c) More than 20% of the population (or of all households) have incomes below the poverty level.

5. *Determination of Insufficient Capacity of Existing Primary Care Providers.*

An area's existing primary care providers will be considered to have insufficient capacity if at least two of the following criteria are met:

(a) More than 8,000 office or outpatient visits per year per FTE primary care physician serving the area.

(b) Unusually long waits for appointments for routine medical services (i.e., more than 7 days for established patients and 14 days for new patients).

(c) Excessive average waiting time at primary care providers (longer than one hour where patients have appointments or two hours where patients are treated on a first-come, first-served basis).

(d) Evidence of excessive use of emergency room facilities for routine primary care.

(e) A substantial proportion (2/3 or more) of the area's physicians do not accept new patients.

(f) Abnormally low utilization of health services, as indicated by an average of 2.0 or less office visits per year on the part of the area's population.

6. *Contiguous Area Considerations.*

Primary care professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Primary care professional(s) in the contiguous area are more than 30 minutes travel time from the population center(s) of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The contiguous area population-to-full-time-equivalent primary care physician ratio is in excess of 2000:1, indicating that practitioners in the contiguous area cannot be expected to help alleviate the shortage situation in the area being considered for designation.

(c) Primary care professional(s) in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers, such as:

(i) Significant differences between the demographic (or socio-economic) characteristics of the area under consideration and those of the contiguous area, indicating that the population of the area under consideration may be effectively isolated from nearby resources. This isolation could be indicated, for example, by an unusually high proportion of non-English-speaking persons.

(ii) A lack of economic access to contiguous area resources, as indicated particularly where a very high proportion of the population of the area under consideration is poor (i.e., where more than 20 percent of the population or the households have incomes below the poverty level), and Medicaid-covered or public primary care services are not available in the contiguous area.

C. *Determination of Degree of Shortage.*

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of full-time equivalent primary care physicians and the presence or absence of unusually high needs for primary health care services, according to the following table:

| | High needs not indicated | High needs indicated |
|---|---|---|
| Group 1 .... | No physicians ..... | No physicians; or R≥5,000 |
| Group 2 .... | R≥5,000 ..... | 5,000>R≥4,000 |
| Group 3 .... | 5,000>R≥4,000 ..... | 4,000>R≥3,500 |
| Group 4 .... | 4,000>R≥3,500 ..... | 3,500>R≥3,000 |

D. *Determination of size of primary care physician shortage.* Size of Shortage (in number of FTE primary care physicians needed) will be computed using the following formulas:

(1) For areas without unusually high need or insufficient capacity:

Primary care physician shortage=area population/3,500−number of FTE primary care physicians

(2) For areas with unusually high need or insufficient capacity:

Primary care physician shortage=area population/3,000−number of FTE primary care physicians

*Part II—Population Groups*

A. *Criteria.*

1. In general, specific population groups within particular geographic areas will be designated as having a shortage of primary medical care professional(s) if the following three criteria are met:

(a) The area in which they reside is rational for the delivery of primary medical care

services, as defined in paragraph B.1 of part I of this appendix.

(b) Access barriers prevent the population group from use of the area's primary medical care providers. Such barriers may be economic, linguistic, cultural, or architectural, or could involve refusal of some providers to accept certain types of patients or to accept Medicaid reimbursement.

(c) The ratio of the number of persons in the population group to the number of primary care physicians practicing in the area and serving the population group is at least 3,000:1.

2. Indians and Alaska Natives will be considered for designation as having shortages of primary care professional(s) as follows:

(a) Groups of members of Indian tribes (as defined in section 4(d) of Pub. L. 94–437, the Indian Health Care Improvement Act of 1976) are automatically designated.

(b) Other groups of Indians or Alaska Natives (as defined in section 4(c) of Pub. L. 94–437) will be designated if the general criteria in paragraph A are met.

B. *Determination of Degree of Shortage.*

Each designated population group will be assigned to a degree-of-shortage group, based on the ratio (R) of the group's population to the number of primary care physicians serving it, as follows:

Group 1—No physicians or R>5,000.
Group 2—5,000>R≥4,000.
Group 3—4,000>R≥3,500.
Group 4—3,500>R≥3,000.

Population groups which have received ''automatic'' designation will be assigned to degree-of-shortage group 4 if no information on the ratio of the number of persons in the group to the number of FTE primary care physicians serving them is provided.

C. *Determination of size of primary care physician shortage.* Size of shortage (in number of primary care physicians needed) will be computed as follows:

Primary care physician shortage=number of persons in population group/3,000−number of FTE primary care physicians

*Part III—Facilities*

A. *Federal and State Correctional Institutions.*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of primary medical care professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE primary care physicians serving the institution is at least 1,000:1. (Here the number of internees is the number of inmates present at the beginning of the year plus the number of new inmates entering the institution during the year, including those who left before the end of the year; the number of FTE primary care physicians is computed as in part I, section B, paragraph 3 above.)

2. *Determination of Degree of Shortage.*

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to primary care physicians, as follows:

Group 1—Institutions with 500 or more inmates and no physicians.
Group 2—Other institutions with no physicians and institutions with R≥2,000.
Group 3—Institutions with 2,000>R≥1,000.

B. *Public or Non-Profit Medical Facilities.*

1. *Criteria.*

Public or non-profit private medical facilities will be designated as having a shortage of primary medical care professional(s) if:

(a) the facility is providing primary medical care services to an area or population group designated as having a primary care professional(s) shortage; and

(b) the facility has insufficient capacity to meet the primary care needs of that area or population group.

2. *Methodology*

In determining whether public or nonprofit private medical facilities meet the criteria established by paragraph B.1 of this Part, the following methodology will be used:

(a) *Provision of Services to a Designated Area or Population Group.*

A facility will be considered to be providing services to a designated area or population group if either:

(i) A majority of the facility's primary care services are being provided to residents of designated primary care professional(s) shortage areas or to population groups designated as having a shortage of primary care professional(s); or

(ii) The population within a designated primary care shortage area or population group has reasonable access to primary care services provided at the facility. Reasonable access will be assumed if the area within which the population resides lies within 30 minutes travel time of the facility and non-physical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

Migrant health centers (as defined in section 319(a)(1) of the Act) which are located in areas with designated migrant population groups and Indian Health Service facilities are assumed to be meeting this requirement.

(b) *Insufficient capacity to meet primary care needs.*

A facility will be considered to have insufficient capacity to meet the primary care needs of the area or population it serves if at

least two of the following conditions exist at the facility:

(i) There are more than 8,000 outpatient visits per year per FTE primary care physician on the staff of the facility. (Here the number of FTE primary care physicians is computed as in Part I, Section B, paragraph 3 above.)

(ii) There is excessive usage of emergency room facilities for routine primary care.

(iii) Waiting time for appointments is more than 7 days for established patients or more than 14 days for new patients, for routine health services.

(iv) Waiting time at the facility is longer than 1 hour where patients have appointments or 2 hours where patients are treated on a first-come, first-served basis.

3. *Determination of Degree of Shortage.*

Each designated medical facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8737, Mar. 2, 1989; 57 FR 2480, Jan. 22, 1992]

## APPENDIX B TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF DENTAL PROFESSIONAL(S)

### *Part I—Geographic Areas*

A. *Federal and State Correctional Institutions.*

1. *Criteria*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of dental professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE dentists serving the institution is at least 1,500:1.

Here the number of internees is defined as follows:

(i) If the number of new inmates per year and the average length-of-stay are not specified, or if the information provided does not indicate that intake dental examinations are routinely performed by dentists upon entry, then—Number of internees=average number of inmates.

(ii) If the average length-of-stay is specified as one year or more, and intake dental examinations are routinely performed upon entry, then—Number of internees=average number of inmates+number of new inmates per year.

(iii) If the average length-of-stay is specified as less than one year, and intake dental examinations are routinely performed upon entry, then—Number of internees=average number of inmates+⅓×(1+2×ALOS)×number of new inmates per year where ALOS=average length-of-stay (in fraction of year).

(The number of FTE dentists is computed as in part I, section B, paragraph 3 above.)

2. Determination of Degree of Shortage.

Designated correctional institutions will be assigned to degree-of-shortage groups based on the number of inmates and/or the ratio (R) of internees to dentists, as follows:

Group 1—Institutions with 500 or more inmates and no dentists.

Group 2—Other institutions with no dentists and institutions with R greater than (or equal to) 3,000:1.

Group 3—Institutions with R greater than (or equal to) 1,500:1 but less than 3,000:1.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Area for the Delivery of Dental Services.*

(a) The following areas will be considered rational areas for the delivery of dental health services:

(i) A county, or a group of several contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county (or an area made up of portions of more than one county) whose population, because of topography, market or transportation patterns, distinctive population characteristics, or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to such resources.

(iii) Established neighborhoods and communities within metropolitan areas which display a strong self-identity (as indicated by a homogenous socioeconomic or demographic structure and/or a traditional of interaction or intradependency), have limited interaction with contiguous areas, and which, in general, have a minimum population of 20,000.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Population Count.*

The population count use will be the total permanent resident civilian population of the area, excluding inmates of institutions, with the following adjustments:

(a) Seasonal residents, i.e., those who maintain a residence in the area but inhabit it for only 2 to 8 months per year, may be included but must be weighted in proportion to the fraction of the year they are present in the area.

(b) Migratory workers and their families may be included in an area's population using the following formula: Effective migrant contribution to population=(fraction of year migrants are present in area)×(average daily number of migrants during portion of year that migrants are present).

3. *Counting of Dental Practitioners.*

(a) All non-Federal dentists providing patient care will be counted, except in those areas where it is shown that specialists (those dentists not in general practice or pedodontics) are serving a larger area and are not addressing the general dental care needs of the area under consideration.

(b) Full-time equivalent (FTE) figures will be used to reflect productivity differences among dental practices based on the age of the dentists, the number of auxiliaries employed, and the number of hours worked per week. In general, the number of FTE dentists will be computed using weights obtained from the matrix in Table 1, which is based on the productivity of dentists at various ages, with different numbers of auxiliaries, as compared with the average productivity of all dentists. For the purposes of these determinations, an auxiliary is defined as any non-dentist staff employed by the dentist to assist in operation of the practice.

TABLE 1—EQUIVALENCY WEIGHTS, BY AGE AND NUMBER OF AUXILIARIES

| | <55 | 55–59 | 60–64 | 65+ |
|---|---|---|---|---|
| No auxiliaries | 0.8 | 0.7 | 0.6 | 0.5 |
| One auxiliary | 1.0 | 0.9 | 0.8 | 0.7 |
| Two auxiliaries | 1.2 | 1.0 | 1.0 | 0.8 |
| Three auxiliaries | 1.4 | 1.2 | 1.0 | 1.0 |
| Four or more auxiliaries | 1.5 | 1.5 | 1.3 | 1.2 |

If information on the number of auxiliaries employed by the dentist is not available, Table 2 will be used to compute the number of full-time equivalent dentists.

TABLE 2—EQUIVALENCY WEIGHTS, BY AGE

| | 55 | 55–59 | 60–64 | 65+ |
|---|---|---|---|---|
| Equivalency weights | 1.2 | 0.9 | 0.8 | 0.6 |

The number of FTE dentists within a particular age group (or age/auxiliary group) will be obtained by multiplying the number of dentists within that group by its corresponding equivalency weight. The total supply of FTE dentists within an area is then computed as the sum of those dentists within each age (or age/auxiliary) group.

(c) The equivalency weights specified in tables 1 and 2 assume that dentists within a particular group are working full-time (40 hours per week). Where appropriate data are available, adjusted equivalency figures for dentists who are semi-retired, who operate a reduced practice due to infirmity or other limiting conditions, or who are available to the population of an area only on a part-time basis will be used to reflect the reduced availability of these dentists. In computing these equivalency figures, every 4 hours (or ½ day) spent in the dental practice will be counted as 0.1 FTE except that each dentist working more than 40 hours a week will be counted as 1.0. The count obtained for a particular age group of dentists will then be multiplied by the appropriate equivalency weight from table 1 or 2 to obtain a full-time equivalent figure for dentists within that particular age or age/auxiliary category.

4. *Determination of Unusually High Needs for Dental Services.*

An area will be considered as having unusually high needs for dental services if at least one of the following criteria is met:

(a) More than 20% of the population (or of all households) has incomes below the poverty level.

(b) The majority of the area's population does not have a fluoridated water supply.

5. *Determination of Insufficient Capacity of Existing Dental Care Providers.*

An area's existing dental care providers will be considered to have insufficient capacity if at least two of the following criteria are met:

(a) More than 5,000 visits per year per FTE dentist serving the area.

(b) Unusually long waits for appointments for routine dental services (i.e., more than 6 weeks).

(c) A substantial proportion (⅔ or more) of the area's dentists do not accept new patients.

6. *Contiguous Area Considerations.*

Dental professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Dental professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with Paragraph B.1.(b) of this part).

(b) Contiguous area population-to-(FTE) dentist ratios are in excess of 3,000:1, indicating that resources in contiguous areas cannot be expected to help alleviate the shortage situation in the area being considered for designation.

(c) Dental professional(s) in the contiguous area are inaccessible to the population of the

area under consideration because of specified access barriers, such as:

(i) Significant differences between the demographic (or socioeconomic) characteristics of the area under consideration and those of the contiguous area, indicating that the population of the area under consideration may be effectively isolated from nearby resources. Such isolation could be indicated, for example, by an unusually high proportion of non-English-speaking persons.

(ii) A lack of economic access to contiguous area resources, particularly where a very high proportion of the population of the area under consideration is poor (i.e., where more than 20 percent of the population or of the households have incomes below the poverty level) and Medicaid-covered or public dental services are not available in the contiguous area.

C. *Determination of Degree of Shortage.*

The degree of shortage of a given geographic area, designated as having a shortage of dental professional(s), will be determined using the following procedure:

Designated areas will be assigned to degree-of-shortage groups, based on the ratio (R) of population to number of full-time-equivalent dentists and the presence or absence of unusually high needs for dental services, or insufficient capacity of existing dental care providers according to the following table:

| | High needs or insufficient capacity not indicated | High needs or insufficient capacity indicated |
|---|---|---|
| Group 1 .... | No dentists ..... | No dentists or R≥8,000. |
| Group 2 .... | R≥8,000 ..... | 8,000>R≥6,000. |
| Group 3 .... | 8,000>R≥6,000 ..... | 6,000>R≥5,000. |
| Group 4 .... | 6,000>R≥5,000 ..... | 5,000>R≥4,000. |

D. *Determination of size of dental shortage.* Size of Dental Shortage (in number of FTE dental practitioners needed) will be computed using the following formulas:

(1) For areas without unusually high need:

Dental shortage=area population/5,000−number of FTE dental practitioners

(2) For areas with unusually high need:

Dental shortage=area population/4,000−number of FTE dental practitioners

*Part II—Population Groups*

A. *Criteria.*

1. In general, specified population groups within particular geographic areas will be designated as having a shortage of dental care professional(s) if the following three criteria are met:

a. The area in which they reside is rational for the delivery of dental care services, as defined in paragraph B.1 of part I of this appendix.

b. Access barriers prevent the population group from use of the area's dental providers.

c. The ratio (R) of the number of persons in the population group to the number of dentists practicing in the area and serving the population group is at least 4,000:1.

2. Indians and Alaska Natives will be considered for designation as having shortages of dental professional(s) as follows:

(a) Groups of members of Indian tribes (as defined in section 4(d) of Pub. L. 94–437, the Indian Health Care Improvement Act of 1976) are automatically designated.

(b) Other groups of Indians or Alaska Natives (as defined in section 4(c) of Pub. L. 94–437) will be designated if the general criteria in paragraph 1 are met.

B. *Determination of Degree of Shortage.*

Each designated population group will be assigned to a degree-of-shortage group as follows:

Group 1—No dentists or R≥8,000.
Group 2—8,000>R≥6,000.
Group 3—6,000>R≥5,000.
Group 4—5,000>R≥4,000.

Population groups which have received ''automatic'' designation will be assigned to degree-of-shortage group 4 unless information on the ratio of the number of persons in the group to the number of FTE dentists serving them is provided.

C. *Determination of size of dental shortage.* Size of dental shortage will be computed as follows:

Dental shortage=number of persons in population group/4,000−number of FTE dental practitioners

*Part III—Facilities*

A. *Federal and State Correctional Institutions.*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as having a shortage of dental professional(s) if both the following criteria are met:

(a) The institution has at least 250 inmates.

(b) The ratio of the number of internees per year to the number of FTE dentists serving the institution is at least 1,500:1. (Here the number of internees is the number of inmates present at the beginning of the year plus the number of new inmates entering the institution during the year, including those who left before the end of the year; the number of FTE dentists is computed as in part I, section B, paragraph 3 above.)

2. *Determination of Degree-of-Shortage.*

Designated correctional institutions will be assigned to degree-of-shortage groups as follows, based on number of inmates and/or the ratio (R) of internees to dentists:

Group 1—Institutions with 500 or more inmates and no dentists.
Group 2—Other institutions with no dentists and institutions with R > 3,000.
Group 3—Institutions with 3,000 > R > 1,500.

B. *Public or Non-Profit Private Dental Facilities.*

1. *Criteria.*

Public or nonprofit private facilties providing general dental care services will be designated as having a shortage of dental professional(s) if both of the following criteria are met:

(a) The facility is providing general dental care services to an area or population group designated as having a dental professional(s) shortage; and

(b) The facility has insufficent capacity to meet the dental care needs of that area or population group.

2. *Methodology.*

In determining whether public or nonprofit private facilities meet the criteria established by paragraph B.1. of this part, the following methodology will be used:

(a) *Provision of Services to a Designated Area or Population Group.*

A facility will be considered to be providing services to an area or population group if either:

(i) A majority of the facility's dental care services are being provided to residents of designated dental professional(s) shortage areas or to population groups designated as having a shortage of dental professional(s); or

(ii) The population within a designated dental shortage area or population group has reasonable access to dental services provided at the facility. Reasonable access will be assumed if the population lies within 40 minutes travel time of the facility and non-physical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

Migrant health centers (as defined in section 319(a)(1) of the Act) which are located in areas with designated migrant population groups and Indian Health Service facilities are assumed to be meeting this requirement.

(b) *Insufficient Capacity To Meet Dental Care Needs.*

A facility will be considered to have insufficient capacity to meet the dental care needs of a designated area or population group if either of the following conditions exists at the facility.

(i) There are more than 5,000 outpatient visits per year per FTE dentist on the staff of the facility. (Here the number of FTE dentists is computed as in part I, section B, paragraph 3 above.)

(ii) Waiting time for appointments is more than 6 weeks for routine dental services.

3. *Determination of Degree of Shortage.*

Each designated dental facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8738, Mar. 2, 1989; 57 FR 2480, Jan. 22, 1992]

## APPENDIX C TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF MENTAL HEALTH PROFESSIONALS

### *Part I—Geographic Areas*

A. *Criteria.* A geographic area will be designated as having a shortage of mental health professionals if the following four criteria are met:

1. The area is a rational area for the delivery of mental health services.

2. One of the following conditions prevails within the area:

(a) The area has—

(i) A population-to-core-mental-health-professional ratio greater than or equal to 6,000:1 and a population-to-psychiatrist ratio greater than or equal to 20,000:1, or

(ii) A population-to-core-professional ratio greater than or equal to 9,000:1, or

(iii) A population-to-psychiatrist ratio greater than or equal to 30,000:1;

(b) The area has unusually high needs for mental health services, and has—

(i) A population-to-core-mental-health-professional ratio greater than or equal to 4,500:1 and

A population-to-psychiatrist ratio greater than or equal to 15,000:1, or

(ii) A population-to-core-professional ratio greater than or equal to 6,000:1, or

(iii) A population-to-psychiatrist ratio greater than or equal to 20,000:1;

3. Mental health professionals in contiguous areas are overutilized, excessively distant or inaccessible to residents of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Mental Health Services.*

(a) The following areas will be considered rational areas for the delivery of mental health services:

(i) An established mental health catchment area, as designated in the State Mental Health Plan under the general criteria set forth in section 238 of the Community Mental Health Centers Act.

(ii) A portion of an established mental health catchment area whose population, because of topography, market and/or transportation patterns or other factors, has limited access to mental health resources in the

rest of the catchment area, as measured generally by a travel time of greater than 40 minutes to these resources.

(iii) A county or metropolitan area which contains more than one mental health catchment area, where data are unavailable by individual catchment area.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions.

3. *Counting of mental health professionals.* (a) All non-Federal core mental health professionals (as defined below) providing mental health patient care (direct or other, including consultation and supervision) in ambulatory or other short-term care settings to residents of the area will be counted. Data on each type of core professional should be presented separately, in terms of the number of full-time-equivalent (FTE) practitioners of each type represented.

(b) Definitions:

(i) *Core mental health professionals* or *core professionals* includes those psychiatrists, clinical psychologists, clinical social workers, psychiatric nurse specialists, and marriage and family therapists who meet the definitions below.

(ii) *Psychiatrist* means a doctor of medicine (M.D.) or doctor of osteopathy (D.O.) who

(A) Is certified as a psychiatrist or child psychiatrist by the American Medical Specialities Board of Psychiatry and Neurology or by the American Osteopathic Board of Neurology and Psychiatry, or, if not certified, is ''broad-eligible'' (i.e., has successfully completed an accredited program of graduate medical or osteopathic education in psychiatry or child psychiatry); and

(B) Practices patient care psychiatry or child psychiatry, and is licensed to do so, if required by the State of practice.

(iii) *Clinical psychologist* means an individual (normally with a doctorate in psychology) who is practicing as a clinical or counseling psychologist and is licensed or certified to do so by the State of practice; or, if licensure or certification is not required in the State of practice, an individual with a doctorate in psychology and two years of supervised clinical or counseling experience. (School psychologists are not included.)

(iv) *Clinical social worker* means an individual who—

(A) Is certified as a clinical social worker by the American Board of Examiners in Clinical Social Work, or is listed on the National Association of Social Workers' Clinical Register, or has a master's degree in social work and two years of supervised clinical experience; and

(B) Is licensed to practice as a social worker, if required by the State of practice.

(v) *Psychiatric nurse specialist* means a registered nurse (R.N.) who—

(A) Is certified by the American Nurses Association as a psychiatric and mental health clinical nurse specialist, or has a master's degree in nursing with a specialization in psychiatric/mental health and two years of supervised clinical experience; and

(B) Is licensed to practice as a psychiatric or mental health nurse specialist, if required by the State of practice.

(vi) *Marriage and family therapist* means an individual (normally with a master's or doctoral degree in marital and family therapy and at least two years of supervised clinical experience) who is practicing as a marital and family therapist and is licensed or certified to do so by the State of practice; or, if licensure or certification is not required by the State of practice, is eligible for clinical membership in the American Association for Marriage and Family Therapy.

(c) Practitioners who provide patient care to the population of an area only on a part-time basis (whether because they maintain another office elsewhere, spend some of their time providing services in a facility, are semi-retired, or operate a reduced practice for other reasons), will be counted on a partial basis through the use of full-time-equivalency calculations based on a 40-hour week. Every 4 hours (or ½ day) spent providing patient care services in ambulatory or inpatient settings will be counted as 0.1 FTE, and each practitioner providing patient care for 40 or more hours per week as 1.0 FTE. Hours spent on research, teaching, vocational or educational counseling, and social services unrelated to mental health will be excluded; if a practitioner is located wholly or partially outside the service area, only those services actually provided within the area are to be counted.

(d) In some cases, practitioners located within an area may not be accessible to the general population of the area under consideration. Practitioners working in restricted facilities will be included on an FTE basis

based on time spent outside the facility. Examples of restricted facilities include correctional institutions, youth detention facilities, residential treatment centers for emotionally disturbed or mentally retarded children, school systems, and inpatient units of State or county mental hospitals.

(e) In cases where there are mental health facilities or institutions providing both inpatient and outpatient services, only those FTEs providing mental health services in outpatient units or other short-term care units will be counted.

(f) Adjustments for the following factors will also be made in computing the number of FTE providers:

(i) Practitioners in residency programs will be counted as 0.5 FTE.

(ii) Graduates of foreign schools who are not citizens or lawful permanent residents of the United States will be excluded from counts.

(iii) Those graduates of foreign schools who are citizens or lawful permanent residents of the United States, and practice in certain settings, but do not have unrestricted licenses to practice, will be counted on a full-time-equivalency basis up to a maximum of 0.5 FTE.

(g) Practitioners suspended for a period of 18 months or more under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act will not be counted.

4. *Determination of unusually high needs for mental health services.* An area will be considered to have unusually high needs for mental health services if one of the following criteria is met:

(a) 20 percent of the population (or of all households) in the area have incomes below the poverty level.

(b) The youth ratio, defined as the ratio of the number of children under 18 to the number of adults of ages 18 to 64, exceeds 0.6.

(c) The elderly ratio, defined as the ratio of the number of persons aged 65 and over to the number of adults of ages 18 to 64, exceeds 0.25.

(d) A high prevalence of alcoholism in the population, as indicated by prevalence data showing the area's alcoholism rates to be in the worst quartile of the nation, region, or State.

(e) A high degree of substance abuse in the area, as indicated by prevalence data showing the area's substance abuse to be in the worst quartile of the nation, region, or State.

5. *Contiguous area considerations.* Mental health professionals in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Core mental health professionals in the contiguous area are more than 40 minutes travel time from the closest population center of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The population-to-core-mental-health-professional ratio in the contiguous area is in excess of 3,000:1 and the population-to-psychiatrist ratio there is in excess of 10,000:1, indicating that core mental health professionals in the contiguous areas are overutilized and cannot be expected to help alleviate the shortage situation in the area for which designation is being considered. (If data on core mental health professionals other than psychiatrists are not available for the contiguous area, a population-to-psychiatrist ratio there in excess of 20,000:1 may be used to demonstrate overutilization.)

(c) Mental health professionals in contiguous areas are inaccessible to the population of the requested area due to geographic, cultural, language or other barriers or because of residency restrictions of programs or facilities providing such professionals.

C. *Determination of degree of shortage.* Designated areas will be assigned to degree-of-shortage groups according to the following table, depending on the ratio ($R_C$) of population to number of FTE core-mental-health-service providers ($FTE_C$); the ratio ($R_P$) of population to number of FTE psychiatrists ($FTE_P$); and the presence or absence of high needs:

High Needs Not Indicated

Group 1—$FTE_C$=0 and $FTE_P$=0
Group 2—$R_C$ gte * 6,000:1 and $FTE_P$=0
Group 3—$R_C$ gte 6,000:1 and $R_P$ gte 20,000
Group 4(a)—For psychiatrist placements only: All other areas with $FTE_P$=0 or $R_P$ gte 30,000
Group 4(b)—For other mental health practitioner placements: All other areas with $R_C$ gte 9,000:1.

*Note: ''gte'' means ''greater than or equal to''.

High Needs Indicated

Group 1—$FTE_C$=0 and $FTE_P$=0
Group 2—$R_C$ gte 4,500:1 and $FTE_P$=0
Group 3—$R_C$ gte 4,500:1 and $R_P$ gte 15,000
Group 4(a)—For psychiatrist placements only: All other areas with $FTE_P$=0 or $R_P$ gte 20,000
Group 4(b)—For other mental health practitioner placements: All other areas with $R_C$ gte 6,000:1.

D. *Determination of Size of Shortage.* Size of Shortage (in number of FTE professionals needed) will be computed using the following formulas:

(1) For areas without unusually high need:

Core professional shortage=area population/6,000 − number of FTE core professionals

Psychiatrist shortage=area population/20,000−number of FTE psychiatrists

(2) For areas with unusually high need:

Core professional shortage=area population/4,500−number of FTE core professionals

Psychiatrist shortage=area population/15,000−number of FTE psychiatrists

*Part II—Population Groups*

A. *Criteria.* Population groups within particular rational mental health service areas will be designated as having a mental health professional shortage if the following criteria are met:

1. Access barriers prevent the population group from using those core mental health professionals which are present in the area; and

2. One of the following conditions prevails:

(a) The ratio of the number of persons in the population group to the number of FTE core mental health professionals serving the population group is greater than or equal to 4,500:1 and the ratio of the number of persons in the population group to the number of FTE psychiatrists serving the population group is greater than or equal to 15,000:1; or,

(b) The ratio of the number of persons in the population group to the number of FTE core mental health professionals serving the population group is greater than or equal to 6,000:1; or,

(c) The ratio of the number of persons in the population group to the number of FTE psychiatrists serving the population group is greater than or equal to 20,000:1.

B. *Determination of degree of shortage.* Designated population groups will be assigned to the same degree-of-shortage groups defined in part I.C of this appendix for areas with unusually high needs for mental health services, using the computed ratio ($R_C$) of the number of persons in the population group to the number of FTE core mental health service providers ($FTE_C$) serving the population group, and the ration ($R_P$) of the number of persons in the population group to the number of FTE psychiatrists ($FTE_P$) serving the population group.

C. *Determination of size of shortage.* Size of shortage will be computed as follows:

Core professional shortage=number of persons in population group/4,500−number of FTE core professionals

Psychiatrist shortage=number of persons in population group/15,000−number of FTE psychiatrists

*Part III—Facilities*

A. *Federal and State Correctional Institutions*

1. *Criteria.*

Medium to maximum security Federal and State correctional institutions for adults or youth, and youth detention facilities, will be designated as having a shortage of psychiatric professional(s) if both of the following criteria are met:

(a) The institution has more than 250 inmates, and

(b) The ratio of the number of internees per year to the number of FTE psychiatrists serving the institution is at least 2,000:1. (Here the number of internees is the number of inmates or residents present at the beginning of the year, plus the number of new inmates or residents entering the institution during the year, including those who left before the end of the year; the number of FTE psychiatrists is computed as in part I, section B, paragraph 3 above.)

2. *Determination of Degree of Shortage.*

Correctional facilities and youth detention facilities will be assigned to degree-of-shortage groups, based on the number of inmates and/or the ratio (R) of internees to FTE psychiatrists, as follows:

Group 1—Facilities with 500 or more inmates or residents and no psychiatrist.

Group 2—Other facilities with no psychiatrists and facilities with 500 or more inmates or residents and R>3,000.

Group 3—All other facilities.

B. *State and County Mental Hospitals.*

1. *Criteria.*

A State or county hospital will be designated as having a shortage of psychiatric professional(s) if both of the following criteria are met:

(a) The mental hospital has an average daily inpatient census of at least 100; and

(b) The number of workload units per FTE psychiatrists available at the hospital exceeds 300, where workload units are calculated using the following formula:

Total workload units = average daily inpatient census + 2 × (number of inpatient admissions per year) + 0.5 × (number of admissions to day care and outpatient services per year).

2. *Determination of Degree of Shortage.*

State or county mental hospitals will be assigned to degree-of-shortage groups, based on the ratio (R) of workload units to number of FTE psychiatrists, as follows:

Group 1—No psychiatrists, or R>1,800.

Group 2—1,800>R>1,200.

Group 3—1,200>R>600.

Group 4—600>R>300.

C. *Community Mental Health Centers and Other Public or Nonprofit Private Facilities.*

1. *Criteria.*

A community mental health center (CMHC), authorized by Pub. L. 94–63, or other public or nonprofit private facility providing mental health services to an area or population group, may be designated as having a shortage of psychiatric professional(s) if the facility is providing (or is responsible for providing) mental health services to an area or population group designated as having a

mental health professional(s), and the facility has insufficient capacity to meet the psychiatric needs of the area or population group.

2. *Methodology.*

In determining whether CMHCs or other public or nonprofit private facilities meet the criteria established in paragraph C.1 of this Part, the following methodology will be used.

(a) *Provision of Services to a Designated Area or Population Group.*

The facility will be considered to be providing services to a designated area or population group if either:

(i) A majority of the facility's mental health services are being provided to residents of designated mental health professional(s) shortage areas or to population groups designated as having a shortage of mental health professional(s); or

(ii) The population within a designated psychiatric shortage area or population group has reasonable access to mental health services provided at the facility. Such reasonable access will be assumed if the population lies within 40 minutes travel time of the facility and nonphysical barriers (relating to demographic and socioeconomic characteristics of the population) do not prevent the population from receiving care at the facility.

(b) *Responsibility for Provision of Services.*

This condition will be considered to be met if the facility, by Federal or State statute, administrative action, or contractual agreement, has been given responsibility for providing and/or coordinating mental health services for the area or population group, consistent with applicable State plans.

(c) *Insufficient capacity to meet mental health service needs.* A facility will be considered to have insufficient capacity to meet the mental health service needs of the area or population it serves if:

(i) There are more than 1,000 patient visits per year per FTE core mental health professional on staff of the facility, or

(ii) There are more than 3,000 patient visits per year per FTE psychiatrist on staff of the facility, or

(iii) No psychiatrists are on the staff and this facility is the only facility providing (or responsible for providing) mental health services to the designated area or population.

3. *Determination of Degree-of-Shortage.*

Each designated facility will be assigned to the same degree-of-shortage group as the designated area or population group which it serves.

[45 FR 76000, Nov. 17, 1980, as amended at 54 FR 8738, Mar. 2, 1989; 57 FR 2477, Jan. 22, 1992]

## APPENDIX D TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VISION CARE PROFESSIONAL(S)

### *Part I—Geographic Areas*

A. *Criteria.*

A geographic area will be designated as having a shortage of vision care professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of vision care services.

2. The estimated number of optometric visits supplied by vision care professional(s) in the area is less than the estimated requirements of the area's population for these visits, and the computed shortage is at least 1,500 optometric visits.

3. Vision care professional(s) in contiguous areas are excessively distant, overutilized, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Vision Care Services.*

(a) The following areas will be considered rational areas for the delivery of vision care services:

(i) A county, or a group of contiguous counties whose population centers are within 40 minutes travel time of each other;

(ii) A portion of a county (or an area made up of portions of more than one county) whose population, because of topography, market or transportation patterns, or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the distance corresponding to 40 minutes travel time.

2. *Determination of Estimated Requirement for Optometric Visits.*

The number of optometric visits required by an area's population will be estimated by multiplying each of the following visit rates by the size of the population within that particular age group and then adding the figures obtained together.

| Age | Annual number of optometric visits required per person, by age | | | | | |
|---|---|---|---|---|---|---|
| | Under 20 | 20–29 | 30–39 | 40–49 | 50–59 | 60 and over |
| Number of visits | 0.11 | 0.20 | 0.24 | 0.35 | 0.41 | 0.48 |

For geographic areas where the age distribution of the population is not known, it will be assumed that the percentage distribution, by age groups, for the area is the same as the distribution for the county of which it is a part.

(3) *Determination of Estimated Supply of Optometric Visits.*

The estimated supply of optometric services will be determined by use of the following formula:

Optometric visits supplied = 3,000 × (number of optometrists under 65)

Optometric visits supplied + 2,000 × (number of optometrists 65 and over)

Optometric visits supplied + 1,500 × (number of ophthamologists)

(4) *Determination of Size of Shortage.*

Size of shortage (in number of optometric visits) will be computed as follows:

Optometric visit shortage = visits required − visits supplied

(5) *Contiguous Area Considerations.*

Vision care professional(s) in area contiguous to an area being considered for designation will be considered execessively distant, overutilized or inaccessible to the population of the area if one of the following conditions prevails in each contiguous area:

(a) Vision care professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph B.1(b) of this part).

(b) The estimated requirement for vision care services in the contiguous area exceeds the estimated supply of such services there, based on the requirements and supply calculations previously described.

(c) Vision care professional(s) in the contiguous area are inaccessible to the population of the area because of specified access barriers (such as economic or cultural barriers).

C. *Determination of Degree-of-Shortage.*

Designated areas (and population groups) will be assigned to degree-of-shortage groups, based on the ratio of optometric visits supplied to optometric visits required for the area (or group), as follows:

Group 1—Areas (or groups) with no optometric visits being supplied (i.e., with no optometrists or ophthalmologists).

Group 2—Areas (or groups) where the ratio of optometric visits supplied to optometric visits required is less than 0.5.

Group 3—Areas (or groups) where the ratio of optometric visits supplied to optometric visits required is between 0.5 and 1.0.

*Part II—Population Groups*

A. *Criteria.*

Population groups within particular geographic areas will be designated if both the following criteria are met:

(1) Members of the population group do not have access to vision care resources within the area (or in contiguous areas) because of non-physical access barriers (such as economic or cultural barriers).

(2) The estimated number of optometric visits supplied to the population group (as determined under paragraph B.3 of part I of this Appendix) is less than the estimated number of visits required by that group (as determined under paragraph B.2 of part I of this Appendix), and the computed shortage is at least 1,500 optometric visits.

B. *Determination of Degree of Shortage.*

The degree of shortage of a given population group will be determined in the same way as described for areas in paragraph C of part I of this appendix.

## APPENDIX E TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PODIATRIC PROFESSIONAL(S)

*Part I—Geographic Areas*

A. *Criteria.*

A geographic area will be designated as having a shortage of podiatric professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of podiatric services.

2. The area's ratio of population to foot care practitioners is at least 28,000:1, and the computed podiatrist shortage to meet this ratio is at least 0.5.

3. Podiatric professional(s) in contiguous areas are overutilized, excessively distant, or inaccessible to the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

1. *Rational Areas for the Delivery of Podiatric Services.*

(a) The following areas will be considered rational areas for the delivery of podiatric services:

(i) A county or a group of contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market and/or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes from its population center to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the area corresponding to 40 minutes travel time.

2. *Population Count.*

The population count used will be the total permanent resident civilian population of the area, excluding inmates of institutions, adjusted by the following formula to take into account the differing utilization rates of podiatric services by different age groups within the population:

Adjusted population=total population × (1 + 2.2 × (percent of population 65 and over) − 0.44 × (percent of population under 17)).

3. *Counting of Foot Care Practitioners.*

(a) All podiatrists providing patient care will be counted. However, in order to take into account productivity differences in podiatric practices associated with the age of the podiatrists, the following formula will be utilized:

Number of FTE podiatrists = 1.0 × (podiatrists under age 55)
+ .8 × (podiatrists age 55 and over)

(b) In order to take into account the fact that orthopedic surgeons and general and family practitioners devote a percentage of their time to foot care, the total available foot care practitioners will be computed as follows:

Number of foot care practitioners = number of FTE podiatrists
+ .15 × (number of orthopedic surgeons)
+ .02 × (number of general and family practioners).

4. *Determination of Size of Shortage.*

Size of shortage (in number of FTE podiatrists) will be computed as follows:

Podiatrist shortage = adjusted population/28,000 − number of FTE foot care practitioners.

5. *Contiguous Area Considerations.*

Podiatric professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant, overutilized or inaccessible to the population of the area under consideration if one of the following conditions prevails in each contiguous area:

(a) Podiatric professional(s) in the contiguous area are more than 40 minutes travel time from the center of the area being considered for designation.

(b) The population-to-foot care practitioner ratio in the contiguous areas is in excess of 20,000:1, indicating that contiguous area podiatric professional(s) cannot be expected to help alleviate the shortage situation in the area for which designation is requested.

(c) Podiatric professional(s) in the contiguous area are inaccessible to the population of the area under consideration because of specified access barriers (such as economic or cultural barriers).

C. *Determination of Degree of Shortage.*

Designated areas will be assigned to groups, based on the ratio (R) of adjusted population to number of foot care practitioners, as follows:

Group 1 Areas with no foot care practitioners, and areas with R > 50,000 and no podiatrists.
Group 2 Other areas with R > 50,000.
Group 3 Areas with 50,000 > R > 28,000.

## APPENDIX F TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PHARMACY PROFESSIONAL(S)

### *Part I—Geographic Areas*

A. *Criteria.*

A geographic area will be designated as having a shortage of pharmacy professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of pharmacy services.

2. The number of pharmacists serving the area is less than the estimated requirement for pharmacists in the area, and the computed pharmacist shortage is at least 0.5.

3. Pharmacists in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

B. *Methodology.*

In determining whether an area meets the criteria established by paragraph A of this Part, the following methodology will be used:

1. *Rational Areas for the Delivery of Pharmacy Services.*

(a) The following areas will be considered rational areas for the delivery of pharmacy services:

(i) A county, or a group of contiguous counties whose population centers are within 30 minutes travel time of each other; and

(ii) A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 30 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 30 minutes travel time:

(i) Under normal conditions with primary roads available: 20 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 15 miles.

(iii) In flat terrain or in areas connected by interstate highways: 25 miles.

Within inner portions of metropolitan areas, information on the public transportation system will be used to determine the area corresponding to 30 minutes travel time.

2. *Counting of Pharmacists.*

All active pharmacists within the area will be counted, except those engaged in teaching, administration, or pharmaceutical research.

3. *Determination of Estimated Requirement for Pharmacists.*

(a) *Basic estimate.* The basic estimated requirement for pharmacists will be calculated as follows:

Basic pharmacist requirement = .15 × (resident civilian population/1,000) + .035 × (total number of physicians engaged in patient care in the area).

(b) *Adjusted estimate.* For areas with less than 20,000 persons, the following adjustment is made to the basic estimate to compensate for the lower expected productivity of small practices.

Estimated pharmacist requirement = (2 − population/20,000) × basic pharmacist requirement.

4. *Size of Shortage Computation.*

The size of the shortage will be computed as follows:

Pharmacist shortage = estimated pharmacist requirement − number of pharmacists available.

5. *Contiguous Area Considerations.*

Pharmacists in areas contiguous to an area being considered for designation will be considered excessively distant or overutilized if either:

(a) Pharmacy professional(s) in contiguous areas are more than 30 minutes travel time from the center of the area under consideration, or

(b) The number of pharmacists in each contiguous area is less than or equal to the estimated requirement for pharmacists for that contiguous area (as computed above).

C. *Determination of Degree-of-Shortage.*

Designated areas will be assigned to degree-of-shortage groups, based on the proportion of the estimated requirement for pharmacists which is currently available in the area, as follows:

Group 1—Areas with no pharmacists.

Group 2—Areas where the ratio of available pharmacists to pharmacists required is less than 0.5.

Group 3—Areas where the ratio of available pharmacists to pharmacists required is between 0.5 and 1.0.

## APPENDIX G TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VETERINARY PROFESSIONAL(S)

### *Part I—Geographic Areas*

A. *Criteria for Food Animal Veterinary Shortage.*

A geographic area will be designated as having a shortage of food animal veterinary professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of veterinary services.

2. The ratio of veterinary livestock units to food animal veterinarians in the area is at least 10,000:1, and the computed food animal veterinarian shortage to meet this ratio is at least 0.5.

3. Food animal veterinarians in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

B. *Criteria for Companion Animal Veterinary Shortage.*

A geographic area will be designated as having a shortage of companion animal veterinary professional(s) if the following three criteria are met:

1. The area is a rational area for the delivery of veterinary services.

2. The ratio of resident civilian population to number of companion animal veterinarians in the area is at least 30,000:1 and the computed companion animal veterinary shortage to meet this ratio is at least 0.5.

3. Companion animal veterinarians in contiguous areas are overutilized or excessively distant from the population of the area under consideration.

C. *Methodology.*

In determining whether an area meets the criteria established by paragraphs A and B of this part, the following methodology will be used:

1. *Rational Areas for the Delivery of Veterinary Services.*

(a) The following areas will be considered rational areas for the delivery of veterinary services:

(i) A county, or a group of contiguous counties whose population centers are within 40 minutes travel time of each other.

(ii) A portion of a county (or an area made up of portions of more than one county) which, because of topography, market and/or transportation patterns or other factors, has limited access to contiguous area resources, as measured generally by a travel time of greater than 40 minutes to these resources.

(b) The following distances will be used as guidelines in determining distances corresponding to 40 minutes travel time:

(i) Under normal conditions with primary roads available: 25 miles.

(ii) In mountainous terrain or in areas with only secondary roads available: 20 miles.

(iii) In flat terrain or in areas connected by interstate highways: 30 miles.

2. *Determination of Number of Veterinary Livestock Units (VLU) Requiring Care.*

Since various types of food animals require varying amounts of veterinary care, each type of animal has been assigned a weight indicating the amount of veterinary care it requires relative to that required by a milk cow. Those weights are used to compute the number of ''Veterinary Livestock Units'' (VLU) for which veterinary care is required.

The VLU is computed as follows:

Veterinary Livestock Units (VLU)=(number of milk cows)
+.2×(number of other cattle and calves)
+.05×(number of hogs and pigs)
+.05×(number of sheep)
+.002×(number of poultry).

3. *Counting of Food Animal Veterinarians.*

The number of food animal veterinarians is determined by weighting the number of veterinarians within each of several practice categories according to the average fraction of practice time in that category which is devoted to food animal veterinary care, as follows:

Number of Food Animal Veterinarians=(number of veterinarians in large animal practice, exclusively)
+(number of veterinarians in bovine practice, exclusively)
+(number of veterinarians in poultry practice, exclusively)
+.75×(mixed practice veterinarians with greater than 50% of practice in large animal care)
+.5×(mixed practice veterinarians with approximately 50% of practice in large animal care)
+.25×(mixed practice veterinarians with less than 50% of practice in large animal care).

4. *Counting of Companion Animal Veterinarians* (that is, those who provide services for dogs, cats, horses, and any other animals maintained as companions to the owner rather than as food animals).

The number of full-time equivalent companion animal veterinarians is determined by weighting the number of veterinarians within each of several practice categories by the average portion of their practice which is devoted to companion animal care by the practitioners within that category, as follows:

Number of Companion Animal Veterinarians=(number of veterinarians in large animal practice, exclusively)
+(number of veterinarians in equine practice, exclusively)
+.75×(mixed practice veterinarians with greater than 50% of practice in small animal care)
+.5×(mixed practice veterinarians with approximately 50% of practice in small animal care)
+.25×(mixed practice veterinarians with less than 50% of practice in small animal care).

5. *Size of Shortage Computation.*

The size of shortage will be computed as follows:

(a) Food animal veterinarian shortage=(VLU/10,000)−(number of food animal veterinarians).

(b) Companion animal veterinarian shortage=(resident civilian pop./30,000)−(number of companion animal veterinarians).

6. *Contiguous Area Considerations.*

Veterinary professional(s) in areas contiguous to an area being considered for designation will be considered excessively distant from the population of the area or overutilized if one of the following conditions prevails in each contiguous area:

(a) Veterinary professional(s) in the contiguous area are more than 60 minutes travel time from the center of the area being considered for designation (measured in accordance with paragraph C.1.(b) of this part).

(b) In the case of food animal veterinary professional(s), the VLU-to-food animal veterinarian ratio in the contiguous area is in excess of 5,000:1.

(c) In the case of companion animal veterinary professional(s), the population-to-companion animal veterinarian ratio in the contiguous area is in excess of 15,000:1.

C. *Determination of Degree-of-Shortage.*

Designated areas will be assigned to degree-of-shortage groups as follows:

Group 1—Areas with a food animal veterinarian shortage and no veterinarians.

Group 2—Areas (not included above) with a food animal veterinarian shortage and no food animal veterinarians.

Group 3—All other food animal veterinarian shortage areas.

Group 4—All companion animal shortage areas (not included above) having no veterinarians.

Group 5—All other companion animal shortage areas.

# PART 6—FEDERAL TORT CLAIMS ACT COVERAGE OF CERTAIN GRANTEES AND INDIVIDUALS

Sec.



AUTHORITY: Sections 215 and 224 of the Public Health Service Act, 42 U.S.C. 216 and 233.

SOURCE: 60 FR 22532, May 8, 1995, unless otherwise noted.

## § 6.1 Applicability.

This part applies to entities and individuals whose acts and omissions related to the performance of medical, surgical, dental, or related functions are covered by the Federal Tort Claims Act (28 U.S.C. 1346(b) and 2671–2680) in accordance with the provisions of section 224(g) of the Public Health Service Act (42 U.S.C. 233(g)).

## § 6.2 Definitions.

*Act* means the Public Health Service Act, as amended.

*Attorney General* means the Attorney General of the United States and any other officer or employee of the Department of Justice to whom the authority involved has been delegated.

*Covered entity* means an entity described in §6.3 which has been deemed by the Secretary, in accordance with §6.5, to be covered by this part.

*Covered individual* means an individual described in §6.4.

*Effective date* as used in §6.5 and §6.6 refers to the date of the Secretary's determination that an entity is a covered entity.

*Secretary* means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of HHS to whom the authority involved has been delegated.

*Subrecipient* means an entity which receives a grant or a contract from a covered entity to provide a full range of health services on behalf of the covered entity.

## § 6.3 Eligible entities.

(a) *Grantees.* Entities eligible for coverage under this part are public and nonprofit private entities receiving Federal funds under any of the following grant programs:

(1) Section 329 of the Act (relating to grants for migrant health centers);

(2) Section 330 of the Act (relating to grants for community health centers);

(3) Section 340 of the Act (relating to grants for health services for the homeless); and

(4) Section 340A of the Act (relating to grants for health services for residents of public housing).

(b) *Subrecipients.* Entities that are subrecipients of grant funds described in paragraph (a) of this section are eligible for coverage only if they provide a full range of health care services on behalf of an eligible grantee and only for those services carried out under the grant funded project.

## § 6.4 Covered individuals.

(a) Officers and employees of a covered entity are eligible for coverage under this part.

(b) Contractors of a covered entity who are physicians or other licensed or certified health care practitioners are eligible for coverage under this part if they meet the requirements of section 224(g)(5) of the Act.

(c) An individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of a covered entity will not be covered for acts or omissions occurring after receipt by the entity employing such individual of notice of a final determination by the Attorney General that he or she is no longer covered by this part, in accordance with section 224(i) of the Act.

## § 6.5 Deeming process for eligible entities.

Eligible entities will be covered by this part only on and after the effective

date of a determination by the Secretary that they meet the requirements of section 224(h) of the Act. In making such determination, the Secretary will receive such assurances and conduct such investigations as he or she deems necessary.

### §6.6 Covered acts and omissions.

(a) Only acts and omissions occurring on and after the effective date of the Secretary's determination under §6.5 and before the later date specified in section 224(g)(3) of the Act are covered by this part.

(b) Only claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions are covered by this part.

(c) With respect to covered individuals, only acts and omissions within the scope of their employment (or contract for services) are covered. If a covered individual is providing services which are not on behalf of the covered entity, such as on a volunteer basis or on behalf of a third-party (except as described in paragraph (d) of this section), whether for pay or otherwise, acts and omissions which are related to such services are not covered.

(d) Only acts and omissions related to the grant-supported activity of entities are covered. Acts and omissions related to services provided to individuals who are not patients of a covered entity will be covered only if the Secretary determines that:

(1) The provision of the services to such individuals benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;

(2) The provision of the services to such individuals facilitates the provision of services to patients of the entity; or

(3) Such services are otherwise required to be provided to such individuals under an employment contract or similar arrangement between the entity and the covered individual.

(e) *Examples.* The following are examples of situations within the scope of paragraph (d) of this section:

(1) A community health center deemed to be a covered entity establishes a school-based or school-linked health program as part of its grant supported activity. Even though the students treated are not necessarily registered patients of the center, the center and its health care practitioners will be covered for services provided, if the Secretary makes the determination in paragraph (d)(1) of this section.

(2) A migrant health center requires its physicians to obtain staff privileges at a community hospital. As a condition of obtaining such privileges, and thus being able to admit the center's patients to the hospital, the physicians must agree to provide occasional coverage of the hospital's emergency room. The Secretary would be authorized to determine that this coverage is necessary to facilitate the provision of services to the grantee's patients, and that it would therefore be covered by paragraph (d)(2) of this section.

(3) A homeless health services grantee makes arrangements with local community providers for after-hours coverage of its patients. The grantee's physicians are required by their employment contracts to provide periodic cross-coverage for patients of these providers, in order to make this arrangement feasible. The Secretary may determine that the arrangement is within the scope of paragraph (d)(3) of this section.

[60 FR 22532, May. 8, 1995; 60 FR 36073, July 13, 1995]

## PART 7—DISTRIBUTION OF REFERENCE BIOLOGICAL STANDARDS AND BIOLOGICAL PREPARATIONS

Sec.
7.1 Applicability.
7.2 Establishment of a user charge.
7.3 Definitions.
7.4 Schedule of charges.
7.5 Payment procedures.
7.6 Exemptions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); title V of the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701); and sec. 352 of the Public Health Service Act, as amended (42 U.S.C. 263).

SOURCE: 52 FR 11073, Apr. 7, 1987, unless otherwise noted.

### § 7.1 Applicability.

The provisions of this part are applicable to private entities requesting from the Centers for Disease Control (CDC) reference biological standards and biological preparations for use in their laboratories.

### § 7.2 Establishment of a user charge.

Except as otherwise provided in §7.6, a user charge shall be imposed to cover the cost to CDC of producing and distributing reference biological standards and biological preparations.

### § 7.3 Definitions.

*Biological standards* means a uniform and stable reference biological substance which allows measurements of relative potency to be made and described in a common currency of international and national units of activity.

*Biological preparations* means a reference biological substance which may be used for a purpose similar to that of a standard, but which has been established without a full collaborative study, or where a collaborative study has shown that it is not appropriate to establish the preparation as an international standard.

### § 7.4 Schedule of charges.

The charges imposed in §7.2 are based on the amount published in CDC's price list of available products. These charges will reflect direct costs (such as salaries and equipment), indirect costs (such as rent, telephone service, and a proportionate share of management and administrative costs), and the costs of particular ingredients. Charges may vary over time and between different biological standards or biological preparations, depending upon the cost of ingredients and the complexity of production. An up-to-date schedule of charges is available from the Biological Products Branch, Center for Infectious Diseases, Centers for Disease Control, 1600 Clifton Road, Atlanta, Georgia 30333.

### § 7.5 Payment procedures.

The requester may obtain information on terms of payment and a fee schedule by writing the ''Centers for Disease Control,'' Financial Management Office, Buckhead Facility, Room 200, Centers for Disease Control, 1600 Clifton Road, Atlanta, Georgia 30333.

### § 7.6 Exemptions.

State and local health departments, governmental institutions (e.g., State hospitals and universities), the World Health Organization, and ministries of health of foreign governments may be exempted from paying user charges, when using biological standards or biological preparations for public health purposes.

## PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS

### Subpart A—Accreditation

Sec.



### Subpart B—Certification and Treatment Standards



### Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

AUTHORITY: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd–2, 300x–23, 300x–27(a), 300y–11.

SOURCE: 66 FR 4090, Jan. 17, 2001, unless otherwise note.

## Subpart A—Accreditation

### §8.1 Scope.

The regulations in this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid addiction. These regulations also establish the Secretary's standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner who intends to dispense opioid drugs in the treatment of opioid addiction must first obtain from the Secretary or by delegation, from the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary's standards for opiate addiction treatment with an opioid agonist treatment medication.

### §8.2 Definitions.

The following definitions apply to this part:

*Accreditation* means the process of review and acceptance by an accreditation body.

*Accreditation body* means a body that has been approved by SAMHSA under §8.3 to accredit opioid treatment programs using opioid agonist treatment medications.

*Accreditation body application* means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body, as described in §8.3(b).

*Accreditation elements* mean the elements or standards that are developed and adopted by an accreditation body and approved by SAMHSA.

*Accreditation survey* means an onsite review and evaluation of an opioid treatment program by an accreditation body for the purpose of determining compliance with the Federal opioid treatment standards described in §8.12.

*Accredited opioid treatment program* means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA under §8.3(d).

*Certification* means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards.

*Certification application* means the application filed by an opioid treatment program for purposes of obtaining certification from SAMHSA, as described in §8.11(b).

*Certified opioid treatment program* means an opioid treatment program that is the subject of a current, valid certification under §8.11.

*Comprehensive maintenance treatment* is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

*Detoxification treatment* means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period.

*Federal opioid treatment standards* means the standards established by the

Secretary in §8.12 that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment. The Federal opioid treatment standards established in §8.12 also include the standards established by the Secretary regarding the quantities of opioid drugs which may be provided for unsupervised use.

*For-cause inspection* means an inspection of an opioid treatment program by the Secretary, or by an accreditation body, that may be operating in violation of Federal opioid treatment standards, may be providing substandard treatment, or may be serving as a possible source of diverted medications.

*Interim maintenance treatment* means maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

*Long-term detoxification treatment* means detoxification treatment for a period more than 30 days but not in excess of 180 days.

*Maintenance treatment* means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid addiction.

*Medical director* means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

*Medical and rehabilitative services* means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), that are intended to help patients in opioid treatment programs become and/or remain productive members of society.

*Medication unit* means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

*Opiate addiction* is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

*Opioid agonist treatment medication* means any opioid agonist drug that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opiate addiction.

*Opioid drug* means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

*Opioid treatment* means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opiate addiction. This term encompasses detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

*Opioid treatment program* or ''OTP'' means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.

*Patient* means any individual who undergoes treatment in an opioid treatment program.

*Program sponsor* means the person named in the application for certification described in §8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or

other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

*Registered opioid treatment program* means an opioid treatment program that is registered under 21 U.S.C. 823(g).

*Short-term detoxification treatment* means detoxification treatment for a period not in excess of 30 days.

*State Authority* is the agency designated by the Governor or other appropriate official designated by the Governor to exercise the responsibility and authority within the State or Territory for governing the treatment of opiate addiction with an opioid drug.

*Treatment plan* means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which specifies the services to be provided and the frequency and schedule for their provision.

### § 8.3 Application for approval as an accreditation body.

(a) *Eligibility.* Private nonprofit organizations or State governmental entities, or political subdivisions thereof, capable of meeting the requirements of this part may apply for approval as an accreditation body.

(b) *Application for initial approval.* Three copies of an accreditation body application form [SMA–163] shall be submitted to SAMHSA at rm. 12–105, 5600 Fishers Lane, Rockville, MD 20857, and marked ATTENTION: OTP Certification Program. SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. Accreditation body applications shall include the following information and supporting documentation:

(1) Name, address, and telephone number of the applicant and a responsible official for the accreditation body. The application shall be signed by the responsible official;

(2) Evidence of the nonprofit status of the applicant (*i.e.,* of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State governmental entity or political subdivision;

(3) A set of the accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid treatment standards set forth in § 8.12;

(4) A detailed description of the applicant's decisionmaking process, including:

(i) Procedures for initiating and performing onsite accreditation surveys of OTPs;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process, including a request for a complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation is true and accurate, and that no material fact has been omitted;

(iv) Policies and procedures for notifying OTPs and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs;

(v) Policies and procedures for suspending or revoking an OTP's accreditation;

(vi) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by SAMHSA; and

(vii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions.

(5) Policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest, by the applicant's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives;

(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership,

and the identification of at least one licensed physician on the applicant's staff;

(7) A description of the applicant's training policies;

(8) Fee schedules, with supporting cost data;

(9) Satisfactory assurances that the body will comply with the requirements of §8.4, including a contingency plan for investigating complaints under §8.4(e);

(10) Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body; and

(11) Any other information SAMHSA may require.

(c) *Application for renewal of approval.* An accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to SAMHSA for renewal, or notify SAMHSA of its intention not to apply for renewal, in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of an accreditation body's term of approval, the body shall inform SAMHSA in writing of its intent to seek renewal.

(2) SAMHSA will notify the applicant of the relevant information, materials, and supporting documentation required under paragraph (b) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 3 months before the date of expiration of the accreditation body's term of approval, the applicant shall furnish to SAMHSA three copies of a renewal application containing the information, materials, and supporting documentation requested by SAMHSA under paragraph (c)(2) of this section.

(4) An accreditation body that does not intend to renew its approval shall so notify SAMHSA at least 9 months before the expiration of the body's term of approval.

(d) *Rulings on applications for initial approval or renewal of approval.* (1) SAMHSA will grant an application for initial approval or an application for renewal of approval if it determines the applicant substantially meets the accreditation body requirements of this subpart.

(2) If SAMHSA determines that the applicant does not substantially meet the requirements set forth in this subpart. SAMHSA will notify the applicant of the deficiencies in the application and request that the applicant resolve such deficiencies within 90 days of receipt of the notice. If the deficiencies are resolved to the satisfaction of SAMHSA within the 90-day time period, the body will be approved as an accreditation body. If the deficiencies have not been resolved to the satisfaction of SAMHSA within the 90-day time period, the application for approval as an accreditation body will be denied.

(3) If SAMHSA does not reach a final decision on a renewal application before the expiration of an accreditation body's term of approval, the approval will be deemed extended until SAMHSA reaches a final decision, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of approval.* An accreditation body that intends to relinquish its accreditation approval before expiration of the body's term of approval shall submit a letter of such intent to SAMHSA, at the address in paragraph (b) of this section, at least 9 months before relinquishing such approval.

(f) *Notification.* An accreditation body that does not apply for renewal of approval, or is denied such approval by SAMHSA, relinquishes its accreditation approval before expiration of its term of approval, or has its approval withdrawn, shall:

(1) Transfer copies of records and other related information as required by SAMHSA to a location, including another accreditation body, and according to a schedule approved by SAMHSA; and

(2) Notify, in a manner and time period approved by SAMHSA, all OTPs accredited or seeking accreditation by the body that the body will no longer have approval to provide accreditation services.

(g) *Term of approval.* An accreditation body's term of approval is for a period not to exceed 5 years.

(h) *State accreditation bodies.* State governmental entities, including political subdivisions thereof, may establish organizational units that may act as accreditation bodies, provided such units meet the requirements of this section, are approved by SAMHSA under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support opioid treatment services.

### § 8.4 Accreditation body responsibilities.

(a) *Accreditation surveys and for cause inspections.* (1) Accreditation bodies shall conduct routine accreditation surveys for initial, renewal, and continued accreditation of each OTP at least every 3 years.

(2) Accreditation bodies must agree to conduct for-cause inspections upon the request of SAMHSA.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved accreditation body application.

(b) *Response to noncompliant programs.* (1) If an accreditation body receives or discovers information that suggests that an OTP is not meeting Federal opioid treatment standards, or if survey of the OTP by the accreditation body otherwise demonstrates one or more deficiencies in the OTP, the accreditation body shall as appropriate either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies.

(i) Accreditation bodies shall either not accredit or shall revoke the accreditation of any OTP that substantially fails to meet the Federal opioid treatment standards.

(ii) Accreditation bodies shall notify SAMHSA as soon as possible but in no case longer than 48 hours after becoming aware of any practice or condition in an OTP that may pose a serious risk to public health or safety or patient care.

(iii) If an accreditation body determines that an OTP is substantially meeting the Federal opioid treatment standards, but is not meeting one or more accreditation elements, the accreditation body shall determine the necessary corrective measures to be taken by the OTP, establish a schedule for implementation of such measures, and notify the OTP in writing that it must implement such measures within the specified schedule in order to ensure continued accreditation. The accreditation body shall verify that the necessary steps are taken by the OTP within the schedule specified and that all accreditation elements are being substantially met or will be substantially met.

(2) Nothing in this part shall prevent accreditation bodies from granting accreditation, contingent on promised programmatic or performance changes, to OTPs with less substantial violations. Such accreditation shall not exceed 12 months. OTPs that have been granted such accreditation must have their accreditation revoked if they fail to make changes to receive unconditional accreditation upon resurvey or reinspection.

(c) *Recordkeeping.* (1) Accreditation bodies shall maintain records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the accreditation body.

(2) Accreditation bodies shall establish procedures to protect confidential information collected or received in their role as accreditation bodies that are consistent with, and that are designed to ensure compliance with, all Federal and State laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to SAMHSA or its duly designated representatives, unless otherwise required by law or with the consent of the OTP.

(ii) Nonpublic information that SAMHSA shares with the accreditation body concerning an OTP shall not be further disclosed except with the written permission of SAMHSA.

(d) *Reporting.* (1) Accreditation bodies shall provide to SAMHSA any documents and information requested by

SAMHSA within 5 days of receipt of the request.

(2) Accreditation bodies shall make a summary of the results of each accreditation survey available to SAMHSA upon request. Such summaries shall contain sufficient detail to justify the accreditation action taken.

(3) Accreditation bodies shall provide SAMHSA upon request a list of each OTP surveyed and the identity of all individuals involved in the conduct and reporting of survey results.

(4) Accreditation bodies shall submit to SAMHSA the name of each OTP for which the accreditation body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to SAMHSA under paragraphs (d)(1) through (d)(4) of this section, each accreditation body shall submit to SAMHSA semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

(6) All reporting requirements listed in this section shall be provided to SAMHSA at the address specified in §8.3(b).

(e) *Complaint response.* Accreditation bodies shall have policies and procedures to respond to complaints from SAMHSA, patients, facility staff, and others, within a reasonable period of time but not more than 5 days of the receipt of the complaint. Accreditation bodies shall also agree to notify SAMHSA within 48 hours of receipt of a complaint and keep SAMHSA informed of all aspects of the response to the complaint.

(f) *Modifications of accreditation elements.* Accreditation bodies shall obtain SAMHSA's authorization prior to making any substantive (*i.e.*, noneditorial) change in accreditation elements.

(g) *Conflicts of interest.* The accreditation body shall maintain and apply policies and procedures that SAMHSA has approved in accordance with §8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the accreditation body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision.

(h) *Accreditation teams.* (1) An accreditation body survey team shall consist of healthcare professionals with expertise in drug abuse treatment and, in particular, opioid treatment. The accreditation body shall consider factors such as the size of the OTP, the anticipated number of problems, and the OTP's accreditation history, in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of drugs subject to control under the Controlled Substances Act (21 U.S.C. 801 *et seq.*);

(ii) Medical issues relating to the dosing and administration of opioid agonist treatment medications for the treatment of opioid addiction;

(iii) Psychosocial counseling of individuals undergoing opioid treatment; and

(iv) Organizational and administrative issues associated with opioid treatment programs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest.

(i) *Accreditation fees.* Fees charged to OTPs for accreditation shall be reasonable. SAMHSA generally will find fees to be reasonable if the fees are limited to recovering costs to the accreditation body, including overhead incurred. Accreditation body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At SAMHSA's request, accreditation bodies shall provide to SAMHSA financial records or other materials, in a manner specified by SAMHSA, to assist in assessing the reasonableness of accreditation body fees.

### § 8.5 Periodic evaluation of accreditation bodies.

SAMHSA will evaluate periodically the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the Federal opioid treatment standards. The evaluation will include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under § 8.6.

### § 8.6 Withdrawal of approval of accreditation bodies.

If SAMHSA determines that an accreditation body is not in substantial compliance with this subpart, SAMHSA shall take appropriate action as follows:

(a) *Major deficiencies.* If SAMHSA determines that the accreditation body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, SAMHSA shall withdraw approval of that accreditation body.

(1) In the event of a major deficiency, SAMHSA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the accreditation body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by SAMHSA.

(b) *Minor deficiencies.* If SAMHSA determines that the accreditation body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, SAMHSA will notify the body that it has 90 days to submit to SAMHSA a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. SAMHSA may place the body on probationary status for a period of time determined by SAMHSA, or may withdraw approval of the body if corrective action is not taken.

(1) If SAMHSA places an accreditation body on probationary status, the body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the accreditation body's probationary status within a time period and in a manner approved by SAMHSA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of SAMHSA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If SAMHSA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, SAMHSA may withdraw approval of the accreditation body. The accreditation body shall notify all OTPs that have been accredited, or are seeking accreditation, of the accreditation body's loss of SAMHSA approval within a time period and in a manner approved by SAMHSA.

(c) *Reapplication.* (1) An accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to SAMHSA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If SAMHSA determines that the new application demonstrates that the

body satisfactorily has addressed the causes of its previous unacceptable performance, SAMHSA may reinstate approval of the accreditation body.

(3) SAMHSA may request additional information or establish additional conditions that must be met before SAMHSA approves the reapplication.

(4) SAMHSA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) *Hearings.* An opportunity to challenge an adverse action taken regarding withdrawal of approval of an accreditation body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in §8.28 for expedited review of an immediate suspension would not apply to an accreditation body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.

## Subpart B—Certification and Treatment Standards

### § 8.11 Opioid treatment program certification.

(a) *General.* (1) An OTP must be the subject of a current, valid certification from SAMHSA to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) to dispense opioid drugs in the treatment of opioid addiction. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense opioid agonist treatment medications to individuals for treatment of opioid addiction.

(2) To obtain certification from SAMHSA, an OTP must meet the Federal opioid treatment standards in §8.12, must be the subject of a current, valid accreditation by an accreditation body or other entity designated by SAMHSA, and must comply with any other conditions for certification established by SAMHSA.

(3) Certification shall be granted for a term not to exceed 3 years, except that certification may be extended during the third year if an application for accreditation is pending.

(b) *Application for certification.* Three copies of an application for certification must be submitted by the OTP to the address identified in §8.3(b). SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. The application for certification shall include:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the control of the OTP;

(5) The sources of funding for the OTP and the name and address of each governmental entity that provides such funding; and

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (f) of this section.

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(c) *Action on application.* (1) Following SAMHSA's receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, SAMHSA may grant the application for certification, or renew an existing certification, if SAMHSA determines that the OTP has satisfied the requirements for certification or renewal of certification.

(2) SAMHSA may deny the application if SAMHSA determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the Federal opioid treatment standards established under §8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification, SAMHSA will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide opioid treatment under section 303(g)(1) of the Controlled Substances Act.

(d) *Transitional certification.* OTPs that before May 18, 2001 were the subject of a current, valid approval by FDA under 21 CFR, part 291 (contained in the 21 CFR parts 200 to 299 edition, revised as of July 1, 2000), are deemed to be the subject of a current valid certification for purposes of paragraph (a)(11) of this section. Such ''transitional certification'' will expire on August 17, 2001 unless the OTP submits the information required by paragraph (b) of this section to SAMHSA on or before August 17, 2001. In addition to this application, OTPs must certify with a written statement signed by the program sponsor, that they will apply for accreditation within 90 days of the date SAMHSA approves the second accreditation body. Transitional certification, in that case, will expire on May 19, 2003. SAMHSA may extend the transitional certification of an OTP for up to one additional year provided the OTP demonstrates that it has applied for accreditation, that an accreditation survey has taken place or is scheduled to take place, and that an accreditation decision is expected within a reasonable period of time (e.g., within 90 days from the date of survey). Transitional certification under this section may be suspended or revoked in accordance with §8.14.

(e) *Provisional certification.* (1) OTPs that have no current certification from SAMHSA, but have applied for accreditation with an accreditation body, are eligible to receive a provisional certification for up to 1 year. To receive a provisional certification, an OTP shall submit the information required by paragraph (b) of this section to SAMHSA along with a statement identifying the accreditation body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. A provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph, unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification.

(2) An extension of provisional certification may be granted in extraordinary circumstances or otherwise to protect public health. To apply for a 90-day extension of provisional certification, an OTP shall submit to SAMHSA a statement explaining its efforts to obtain accreditation and a schedule for obtaining accreditation as expeditiously as possible.

(f) *Conditions for certification.* (1) OTPs shall comply with all pertinent State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of opioid drugs in the treatment of opioid addiction. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States. Federal agencies operating OTPs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal OTPs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, by the DEA, and by authorized employees of any relevant State or Federal governmental authority.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2, and

every program must comply with that part. Records on the receipt, storage, and distribution of opioid agonist treatment medications are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*). Federally-sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of SAMHSA to have access to and to copy all records on the use of opioid drugs in accordance with the provisions of 42 CFR part 2.

(5) OTPs shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II, and must be registered by the DEA before administering or dispensing opioid agonist treatment medications.

(7) OTPs must operate in accordance with Federal opioid treatment standards and approved accreditation elements.

(g) *Conditions for interim maintenance treatment program approval.* (1) Before a public or nonprofit private OTP may provide interim maintenance treatment, the program must receive the approval of both SAMHSA and the chief public health officer of the State in which the OTP operates.

(2) Before SAMHSA may grant such approval, the OTP must provide SAMHSA with documentation from the chief public health officer of the State in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim maintenance treatment in the State;

(ii) The OTP seeking to provide such treatment is unable to place patients in a public or nonprofit private comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek admission to such programs;

(iii) The authorization of the OTP to provide interim maintenance treatment will not otherwise reduce the capacity of comprehensive maintenance treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and

(iv) The State certifies that each individual enrolled in interim maintenance treatment will be transferred to a comprehensive maintenance treatment program no later than 120 days from the date on which each individual first requested treatment, as provided in section 1923 of the Public Health Service Act (21 U.S.C. 300x-23).

(3) SAMHSA will provide notice to the OTP denying or approving the request to provide interim maintenance treatment. The OTP shall not provide such treatment until it has received such notice from SAMHSA.

(h) *Exemptions.* An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the regulatory requirements set forth under this section and §8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

(i) *Medication units, long-term care facilities and hospitals.* (1) Certified OTPs may establish medication units that are authorized to dispense opioid agonist treatment medications for observed ingestion. Before establishing a medication unit, a certified OTP must notify SAMHSA by submitting form SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent state laws and regulations.

(2) Certification as an OTP under this part will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility. The terms ''hospital'' and ''long-term care facility'' as used in this section are to have the meaning that is assigned under the law of the State in which the treatment is being provided. Nothing in this section is intended to relieve hospitals and long-term care facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

[66 FR 4090, Jan. 17, 2001, as amended at 66 FR 15347, Mar. 19, 2001]

### §8.12 Federal opioid treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current ''Diversion Control Plan'' or ''DCP'' as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials.* Each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

(e) *Patient admission criteria.*—(1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by

the relevant State authority consents in writing to such treatment.

(3) Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) Detoxification treatment. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) *Required services.*—(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) Special services for pregnant patients. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) *Recordkeeping and patient confidentiality.* (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

(i) Methadone;

(ii) Levomethadyl acetate (LAAM); and

(iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid addiction.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with

the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) Unsupervised or ''take-home'' use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, e.g., drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91–601 (15 U.S.C. 1471 *et seq.*)).

(j) *Interim maintenance treatment.* (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days

of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of §8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or ''take-home'' use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

[66 FR 4090, Jan. 17, 2001, as amended at 68 FR 27939, May 22, 2003]

### §8.13 Revocation of accreditation and accreditation body approval.

(a) *SAMHSA action following revocation of accreditation.* If an accreditation body revokes an OTP's accreditation, SAMHSA may conduct an investigation into the reasons for the revocation. Following such investigation, SAMHSA may determine that the OTP's certification should no longer be in effect, at which time SAMHSA will initiate procedures to revoke the facility's certification in accordance with §8.14. Alternatively, SAMHSA may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation body approval.* (1) If SAMHSA withdraws the approval of an accreditation body under §8.6, the certifications of OTPs accredited by such body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the accreditation body, unless SAMHSA determines that to protect public health or safety, or because the accreditation body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. SAMHSA may extend the time in which a certification remains in effect under this paragraph on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by SAMHSA, OTPs currently accredited by the accreditation body must obtain accreditation from another accreditation body. SAMHSA may extend the time period for obtaining reaccreditation on a case-by-case basis.

### § 8.14 Suspension or revocation of certification.

(a) *Revocation.* Except as provided in paragraph (b) of this section, SAMHSA may revoke the certification of an OTP if SAMHSA finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with subpart C of this part, that the program sponsor, or any employee of the OTP:

(1) Has been found guilty of misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal opioid treatment standards in any respect;

(3) Has failed to comply with reasonable requests from SAMHSA or from an accreditation body for records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal opioid treatment standards; or

(4) Has refused a reasonable request of a duly designated SAMHSA inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or accreditation body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever SAMHSA has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, SAMHSA may immediately suspend the certification of an OTP before holding a hearing under subpart C of this part. SAMHSA may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under subpart C of this part if SAMHSA makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal opioid treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal opioid treatment standards was intentional or was associated with fraud.

(c) *Written notification.* In the event that SAMHSA suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, SAMHSA shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action and shall state that the OTP may seek review of the action in accordance with the procedures in subpart C of this part.

(d)(1) If SAMHSA suspends certification in accordance with paragraph (b) of this section:

(i) SAMHSA will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) SAMHSA will provide an opportunity for a hearing under subpart C of this part.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

### § 8.15 Forms.

(a) SMA–162—Application for Certification to Use Opioid Agonist Treatment Medications for Opioid Treatment.

(b) SMA–163—Application for Becoming an Accreditation Body under §8.3.

## Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

### § 8.21 Applicability.

The procedures in this subpart apply when:

(a) SAMHSA has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that SAMHSA proposes to revoke the certification; and

(b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing an opportunity for a review of the suspension or proposed revocation.

(c) SAMHSA has notified an accreditation body of an adverse action taken regarding withdrawal of approval of the accreditation body under the regulations in subpart A of this part; and

(d) The accreditation body has, within 30 days of the date of the notification, requested in writing an opportunity for a review of the adverse action.

### § 8.22 Definitions.

The following definitions apply to this subpart C.

(a) *Appellant* means:

(1) The treatment program which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation, or

(2) The accreditation body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.

(b) *Respondent* means SAMHSA.

(c) *Reviewing official* means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more HHS officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

### § 8.23 Limitation on issues subject to review.

The scope of review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts the regulations, in the subpart, and other relevant law.

### § 8.24 Specifying who represents the parties.

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

### § 8.25 Informal review and the reviewing official's response.

(a) *Request for review.* Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension, proposed revocation, or adverse action, a brief statement of why the decision to suspend, propose revocation, or take an adverse action is incorrect, and the appellant's request for an oral presentation, if desired.

(b) *Acknowledgment.* Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

### § 8.26 Preparation of the review file and written arguments.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review

file and submission of written argument are:

(a) *Appellant's documents and brief.* Within 30 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification or to take adverse action regarding withdrawal of approval of the accreditation body is incorrect (appellant's brief).

(b) *Respondent's documents and brief.* Within 30 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification, or approval as an accreditation body, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension, proposed revocation, or adverse action (respondent's brief).

(c) *Reply briefs.* Within 10 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive documentation.* The reviewing official may take any appropriate steps to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

(f) *Discovery.* The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

### § 8.27 Opportunity for oral presentation.

(a) *Electing oral presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decisionmaking process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and place of oral presentation.* The presiding official will attempt to schedule the oral presentation within 45 days of the date appellant's request for review is received or within 15 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the oral presentation.*—(1) General. The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more HHS officers or employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) Burden of proof/standard of proof. In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend, propose revocation, or take adverse action is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) Admission of evidence. The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the pre-hearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) Motions. The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) Transcripts. The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of justice or making of false statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1001 or 1505.

(g) *Post-hearing procedures.* At the presiding official's discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

### § 8.28 Expedited procedures for review of immediate suspension.

(a) *Applicability.* When the Secretary notifies a treatment program in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 10 days of the date the OTP received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing official's response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review file and briefs.* Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with §8.27(a), the presiding official will attempt to schedule the oral presentation within 20 to 30 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with §8.27(c) and will conduct the oral presentation in accordance with the procedures of §§8.27(e), (f), and (g).

(e) *Written decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in §8.33 apply.

(f) *Transmission of written communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.

### § 8.29 Ex parte communications.

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

### § 8.30 Transmission of written communications by reviewing official and calculation of deadlines.

(a) *Timely review.* Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, or commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) *Due date.* In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

### § 8.31 Authority and responsibilities of the reviewing official.

In addition to any other authority specified in this subpart C, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of the procedures in this subpart.

### § 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

### § 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis

for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the FEDERAL REGISTER. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the FEDERAL REGISTER. SAMHSA will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

### § 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under §8.28(e) or §8.33(a), constitutes final agency action as of the date of the decision.